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IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

ARBUTUS BIOPHARMA CORP. and GENEVANT SCIENCES GMBH, Plaintiffs, v. PFIZER INC. and BIONTECH SE, Defendants.	Civil Action No. 3:23-cv-1876-ZNQ-TJB *Document Filed Electronically* **JURY TRIAL DEMANDED**
PFIZER INC. and BIONTECH SE, Counterclaimants, v. ARBUTUS BIOPHARMA CORP. and GENEVANT SCIENCES GMBH, Counterclaim-Defendants.	**PFIZER INC. AND BIONTECH SE'S ANSWER, AFFIRMATIVE DEFENSES, AND COUNTERCLAIMS IN RESPONSE TO COMPLAINT FOR PATENT INFRINGEMENT**

Defendants Pfizer Inc. ("Pfizer") and BioNTech SE ("BioNTech") (collectively, "Defendants") hereby answer the Complaint for Patent Infringement ("Complaint") filed by

Plaintiffs Arbutus Biopharma Corp. ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively, "Plaintiffs"). Any allegations not expressly admitted are denied. This answer follows the numbering provided in Plaintiffs' Complaint. To the extent that the section headings of Plaintiffs' Complaint contain allegations, those allegations are denied. To the extent Plaintiffs' footnotes contain allegations, those allegations are denied.

INTRODUCTION

1. Arbutus invented and was awarded numerous patents on the breakthrough lipid nanoparticle ("LNP") technologies needed to deliver messenger ribonucleic acid ("mRNA") therapeutics to human cells. Genevant, a world leader in nucleic acid drug delivery and development, licenses these patents from Arbutus.

RESPONSE: Defendants admit that the Patent and Trademark Office issued United States Patent Nos. 9,504,651; 8,492,359; 11,141,378; 11,298,320; and 11,318,098 (collectively, the "Asserted Patents"), but deny that the Asserted Patents are valid or infringed by Defendants. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 1 and therefore deny the allegations.

2. When the world was thrust into a devastating pandemic and urgently needed LNP technologies to deliver an mRNA-based COVID-19 vaccine to cells in the body, the necessary LNP technologies had, fortunately, already been invented by Arbutus's scientists years before and stood ready for use. Defendants could not have accomplished the feat of creating and manufacturing a vaccine at a speed unprecedented in the history of medicine but for their use of Plaintiffs' existing and proven LNP technologies. Yet Defendants never paid Plaintiffs to use those technologies. And Defendants continue to knowingly use the technologies to make and sell the vaccine, amassing tens of billions of dollars in revenues. Plaintiffs have thus filed this case to obtain fair compensation for their inventions, without which the vaccine would not exist.

RESPONSE: Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 2 and therefore deny the allegations.

3. Defendants' vaccine works by delivering a synthetic mRNA to the body's cells. The biggest technological barrier to mRNA-based medicines is not the mRNA itself—BioNTech's

CEO designed the mRNA over a weekend. The biggest barrier is instead how to *deliver* the mRNA to cells safely and effectively. As Pfizer's CEO Albert Bourla has explained, "[t]he whole mRNA [vaccine] platform is not how to build an mRNA molecule; ***that's the easy thing***." The hard thing is "***how to make sure the mRNA molecule will go into your cells*** and give the instructions."[1] A Nobel Prize-winner has similarly explained that the key to RNA therapeutics was "***delivery, delivery, delivery***."[2]

RESPONSE: To the extent the allegations of Paragraph 3 purport to rely on public statements, those statements speak for themselves. Defendants admit that Defendants' vaccine (referred to herein by its trade name Comirnaty®) contains synthetic mRNA. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 3 and therefore deny the allegations.

4. The delivery problem had persisted for decades until a team of Arbutus scientists, many now at Genevant companies, developed and refined technologies that solved the problem, for which they were awarded many patents. Their solution involved microscopic particles, built from four carefully-selected types of fat-like molecules, that are stable enough to shelter and protect fragile ribonucleic acid ("RNA") molecules on a voyage through the human body to a target cell, and then through the target cell's membrane, before finally releasing the RNA. These particles are called lipid nanoparticles and their invention was widely recognized as a major achievement that is essential for mRNA vaccines.

RESPONSE: Defendants admit that the Asserted Patents were issued, but deny that the Asserted Patents are valid or infringed by Defendants. At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 4 and therefore deny the allegations.

5. Arbutus also developed the technologies needed to manufacture these LNPs. Before Arbutus's scientists tackled the manufacturing challenges, methods of manufacturing LNPs for RNA employed harsh conditions that would damage the RNA that the LNPs were supposed to protect. Arbutus's scientists developed new, elegant manufacturing methods that preserved the

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[1] Nathan Vardi, *Covid's Forgotten Hero: The Untold Story Of The Scientist Whose Breakthrough Made The Vaccines Possible*, Forbes, Aug. 17, 2021 (https://tinyurl.com/86ud83kj).

[2] Erika Check, *RNA to the Rescue?*, Nature, 425:10-12 (2003) (www.nature.com/articles/425010a).

RNA and allowed for it to reach target cells in an undamaged state. Their solution used what is called a T-connector to mix together flows of lipids and dissolved RNAs in a process that ensures the RNA is both encapsulated and protected during the formulation process.

RESPONSE: At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 5 and therefore deny the allegations.

6. Defendants have long recognized the value of Plaintiffs' LNP technologies and patent rights. For example, in 2018, BioNTech paid for a license to use the technologies in a contract that described Genevant's platform as "the best lipid nanoparticle technology." The license only permitted BioNTech to use the technology in specific cancer and rare liver disease treatments and did not extend to uses for infectious diseases like COVID-19. Pfizer, on information and belief, has long known about that license and Plaintiffs' patents. Yet neither BioNTech nor Pfizer asked for a license to use Plaintiffs' LNP technologies in a COVID-19 vaccine. They just used the technologies without paying for them—keeping for themselves tens of billions in revenue that would never have existed were it not for Plaintiffs' innovation.

RESPONSE: Defendants admit that there is a license agreement between BioNTech and Genevant, which speaks for itself. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. Defendants deny the remaining allegations of Paragraph 6.

7. Plaintiffs have licensed their technologies to many companies and would have granted a license to Defendants on reasonable terms for use in a COVID-19 vaccine. Indeed, the parties engaged in licensing discussions that unfortunately failed to result in a settlement. Plaintiffs have therefore been left no choice but to file this lawsuit to seek fair compensation in the form of a reasonable royalty for Defendants' unlicensed use of Plaintiffs' patents.

RESPONSE: Defendants admit that Plaintiffs sent a letter to Pfizer copying BioNTech on November 23, 2020, and that Defendants have not entered into a license with Plaintiffs. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 7 and therefore deny the allegations.

NATURE OF THE ACTION

8. This is a civil action by Plaintiffs against Defendants under the patent laws of the United States, 35 U.S.C. § 101 *et seq.*, seeking damages for Defendants' infringing manufacture, use, sale, offer for sale, and/or importation of their COVID-19 vaccine and any COVID-19 mRNA-LNP vaccine products, including: pediatric doses; booster doses; supplemental doses; reformulations; boosters or re-vaccinations; variant-specific formulations; bivalent formulations; and the products known or marketed as Pfizer-BioNTech SE (BioNTech) COVID-19 vaccine, Comirnaty, Tozinameran, BNT162b2, or PF-07302048 (collectively, the "Accused Product" or "Defendants' vaccine").

RESPONSE: Paragraph 8 states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that the Complaint purports to state a claim for infringement arising under 35 U.S.C. § 1, *et seq.* for the sale of Comirnaty® but deny that they have infringed or will infringe, directly or indirectly, the Asserted Patents. Defendants deny the remaining allegations of Paragraph 8.

9. Defendants' manufacture, use, sale, offer to sell, and/or importation of the Accused Product directly and/or indirectly infringes or will infringe, or actively induces or will actively induce infringement of, one or more valid enforceable claims of, and Plaintiffs' rights arising under, the following patents relating to nucleic acid-lipid particles, compositions thereof, their manufacture, and/or their use to deliver mRNA and/or other nucleic acid-based medicines: U.S. Patent Nos. 9,504,651 (Exhibit A); 8,492,359 (Exhibit B); 11,141,378 (Exhibit C); 11,298,320 (Exhibit D); and 11,318,098 (Exhibit E) (collectively, the "Asserted Patents"). At all relevant times, Arbutus owned the Asserted Patents and licensed exclusive rights to sublicense, practice, and sue for infringement of them to Genevant in certain fields of use that include the vaccine application at issue in this Complaint, with certain exceptions not relevant here (hereinafter, Genevant's "Exclusive Rights").

RESPONSE: Defendants admit that Exhibits A through E are documents that purport to be copies of the Asserted Patents, but deny that the Asserted Patents are valid and enforceable. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 9 and therefore deny the allegations.

PARTIES

10. Plaintiff Arbutus Biopharma Corporation is a Canadian corporation with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania, 18974. The

company's research and development efforts include discovering, developing, and commercializing a cure for chronic hepatitis B virus, as well as drug discovery and development for treating coronaviruses, including SARS-CoV-2, which causes COVID-19.

RESPONSE: On information and belief, Defendants admit that Arbutus is a Canadian corporation with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania 18974. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 10 and therefore deny the allegations.

11. Plaintiff Genevant Sciences GmbH is a Swiss company with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland. Together with its affiliated companies, it maintains an office in Cambridge, Massachusetts, and Vancouver, British Columbia. Genevant is a technology-focused nucleic acid delivery solutions company with cutting-edge LNP platforms. Genevant owns or licenses the industry's most important LNP intellectual property—that of Arbutus—and has decades of experience and expertise in nucleic acid drug delivery and development. Genevant's mission is to utilize its LNP and other technologies to deliver innovative new medicines that use mRNA or other nucleic acids.

RESPONSE: On information and belief, Defendants admit that Genevant Sciences GmbH is a Swiss company with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland and maintains, through its affiliated companies, offices in Cambridge, Massachusetts and Vancouver, British Columbia. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 11 and therefore deny the allegations.

12. Defendant Pfizer is a Delaware corporation with its principal place of business in New York City and significant operations in New Jersey. According to Pfizer's 2022 annual report, Pfizer's global supply "leadership teams" are located primarily in New York City and New Jersey.

RESPONSE: Defendants admit that Pfizer is incorporated in Delaware with a principal place of business in New York City and business operations in New Jersey. Pfizer's 2022 annual report speaks for itself. Defendants deny the remaining allegations of Paragraph 12.

13. Defendant BioNTech SE is a German corporation with its principal place of business in Germany and its North American headquarters in Cambridge, Massachusetts.

RESPONSE: Defendants admit that BioNTech SE is a German corporation with its principal place of business in Germany. Defendants deny the remaining allegations of Paragraph 13.

14. Pfizer and BioNTech are and have been operating jointly and as agents of one another as to Defendants' vaccine and share equally in profits from sales of the vaccine. For example:

- A March 17, 2020, Collaboration Agreement reflects Pfizer and BioNTech's agreement to engage in "collaborative research and development" to develop and launch a Covid-19 vaccine "in all countries of the Territory," and their "wish that Pfizer Commercialize[] the Product in all countries of the Territory," where (i) "Commercialize" is defined as "market, promote, distribute, offer for sale, sell, have sold, import, have imported, export, have exported or otherwise commercialize a compound or product," and (ii) "Territory" is defined to include the United States.

- Pfizer's 2022 annual report, published on or about February 23, 2023, states that Pfizer and BioNTech have been "collaborat[ing]" to "jointly develop[] and commercialize[]" the vaccine; discusses "Comirnaty-related manufacturing activities performed [by Pfizer] on behalf of BioNTech"; and explains that Pfizer and BioNTech "equally share the costs of development" and "share gross profits equally from commercialization." Similarly, Pfizer and BioNTech's press releases have stated that "BioNTech is the Marketing Authorization Holder [for the vaccine]… and the holder of emergency use authorizations … in the United States (jointly with Pfizer)."

- In a Complaint filed July 25, 2022, Pfizer and BioNTech alleged that they "partnered together, and continue to work together" on the vaccine; "partnered together to develop, manufacture, and secure regulatory approval" of the vaccine, including as to "clinical testing [and] distribution"; and "agreed to share the costs of developing" the vaccine. The Complaint also alleges that "Pfizer, on behalf of itself and BioNTech, submitted clinical trial data as part of an Emergency Use Authorization ('EUA') request to the FDA for administering the Pfizer-BioNTech COVID-19 vaccine…."[3]

RESPONSE: Paragraph 14 states a legal conclusion to which no response is required. To the extent a response is required, the allegations of Paragraph 14 purport to rely on a March 17, 2020 Collaboration Agreement, Pfizer's 2022 annual report, and the Complaint filed on July 25, 2022 in *BioNTech SE v. CureVac AG*, No. 22-11202 (D. Mass.), since transferred as *BioNTech SE*

[3] Complaint, *BioNTech SE, BioNTech Manufacturing GMBH, and Pfizer Inc. v. Curevac AG*, Case No. 1:22-cv-11202 (D. Mass. July 25, 2022) at ⁋⁋ 1, 2, 48, 49, 55.

v. CureVac AG, No. 23-222 (E.D. Va.), which speak for themselves. Defendants deny the remaining allegations of Paragraph 14.

JURISDICTION AND VENUE

A. Subject Matter Jurisdiction

15. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331 and 1338(a) because this is an action for infringement under the patent laws of the United States, Title 35 of the United States Code.

RESPONSE: Paragraph 15 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action only, they do not contest that this Court has subject matter jurisdiction over this action.

B. Personal Jurisdiction

16. This Court has personal jurisdiction over Pfizer because it maintains a regular and established place of business in this District.

RESPONSE: Paragraph 16 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest personal jurisdiction.

17. This Court has personal jurisdiction over both Pfizer and BioNTech because they transact business relating to Plaintiffs' claims in this District, engage in systematic and continuous business contacts here, and have purposefully availed themselves of the benefits and protections of New Jersey's laws such that they should reasonably anticipate being haled into court here.

RESPONSE: Paragraph 17 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest personal jurisdiction. Defendants otherwise deny the remaining allegations of Paragraph 17.

18. Among other things, Pfizer and BioNTech operate jointly and/or as agents of one another to develop, manufacture, import, market, distribute, offer to sell, and/or sell the Accused Product in the State of New Jersey and throughout the United States, for use in the State of New Jersey and throughout the United States. Directly or through others, Pfizer and BioNTech make, use, induce others to use, offer for sale, and/or sell the Accused Product within the United States,

and/or import the same into the United States, including into the District of New Jersey. They have also contracted with one another with the purpose and intent of inducing and participating in sales of the Accused Product in the United States, including in this State and District.

RESPONSE: Paragraph 18 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest personal jurisdiction. Defendants otherwise deny the remaining allegations of Paragraph 18.

19. For example, on December 11, 2020, Defendants received Emergency Use Authorization ("EUA") from the United States Food and Drug Administration ("FDA") for Defendants' vaccine to be distributed and administered to people 16 years of age and older throughout the United States, including in the District of New Jersey, and, on August 23, 2021, the FDA approved Defendants' Biologics License Application ("BLA") for the vaccine. Upon information and belief, as of April 2, 2023, more than 11.9 million doses of Defendants' vaccine have been administered in the State of New Jersey.[4] Therefore, Pfizer and BioNTech transact business within New Jersey relating to Plaintiffs' claims and have engaged in systematic and continuous business contacts here.

RESPONSE: Paragraph 19 states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that on December 11, 2020, the FDA granted an EUA for Defendants' vaccine. Defendants also admit that on August 23, 2021, the FDA approved the BLA for Comirnaty®. Defendants also respond that, solely for purposes of this action and solely for the claims asserted in the Complaint, they do not contest personal jurisdiction. Defendants otherwise deny the remaining allegations of Paragraph 19.

20. For the above reasons, there is nothing unreasonable or fundamentally unfair about requiring Pfizer and BioNTech to litigate this action in this District, and the Court has personal jurisdiction over them here.

RESPONSE: Paragraph 20 states legal conclusions to which no response is required. To the extent a response is required, Defendants respond that, solely for purposes of this action and

[4] https://www.nj.gov/health/cd/topics/covid2019_dashboard.shtml.

solely for the claims asserted in the Complaint, they do not contest personal jurisdiction. Defendants otherwise deny the remaining allegations of Paragraph 20.

C. Venue

21. Venue is proper in this District as to Pfizer pursuant to 28 U.S.C. § 1400(b) because Pfizer has committed acts of infringement in this District and has a regular and established place of business in this District. Among other things, Pfizer has committed acts of infringement in this District by making, using, selling, and/or offering for sale in this District the Accused Product and inducing others to use the Accused Product in this District. Moreover, Pfizer has a campus in this District, where leadership teams are located.

RESPONSE: Paragraph 21 states legal conclusions to which no response is required. To the extent a response is required, Pfizer responds that, solely for purposes of this action and solely for the claims asserted in the Complaint, Pfizer does not contest venue. Defendants otherwise deny the remaining allegations of Paragraph 21.

22. Venue is proper in this District as to BioNTech pursuant to 28 U.S.C. §§ 1400 and 1391 because it is subject to personal jurisdiction here.

RESPONSE: Paragraph 22 states legal conclusions to which no response is required. To the extent a response is required, BioNTech responds that, solely for purposes of this action and solely for the claims asserted in the Complaint, BioNTech does not contest venue. Defendants otherwise deny the remaining allegations of Paragraph 22.

BACKGROUND

A. Nucleic Acids

23. Defendants' vaccine belongs to a new class of medicines that delivers nucleic acids, such as mRNA, into the cells of the body to treat diseases or, in the case of Defendants' vaccine, to trigger an immune response to protect a person from future infection.

RESPONSE: Defendants admit that Comirnaty®, when properly administered, has been shown to have the ability to deliver mRNA into certain cells of a patient to trigger an immune response. At least because of the scope, breadth, and vagueness of this allegation, Defendants

otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 23 and therefore deny the allegations.

24. Nucleic acids are molecules that encode the genetic information essential to sustain all forms of life. One type of nucleic acid is deoxyribonucleic acid, or "DNA." Every human (except identical twins) has a unique set of genetic information in the "genes" (composed of DNA) within his or her chromosomes. Among other things, these genes spell out the instructions for producing proteins that make human cells and bodies function.

RESPONSE: Defendants admit that nucleic acids, such as DNA, can encode genetic information. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 24 and therefore deny the allegations.

25. In order to make the protein encoded by a particular gene, cells first convert the genetic code in the gene's DNA into another type of nucleic acid known as messenger ribonucleic acid, or "mRNA." mRNA is effectively a copy of the portion of DNA that the cell's protein-making machinery uses as a blueprint to assemble the protein encoded by the gene.

RESPONSE: Defendants admit that DNA can be transcribed to produce RNA, which can encode proteins. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 25 and therefore deny the allegations.

B. How Vaccines Work

26. A virus is typically a small packet of DNA or RNA. If a virus enters a living host cell—for example, after being ingested, transmitted through bodily fluids, or inhaled through a person's mouth or nose—the virus's DNA or RNA hijacks the cell's machinery and instructs the cell to make copies of the virus. These copies, often numbering into the millions, leave the infected cell and enter other cells where the process repeats. Infected cells can be damaged or die while hosting the virus. Left unchecked, the host organism itself can die.

RESPONSE: Defendants admit that a virus typically contains DNA or RNA. Defendants also admit that a virus may enter a living host cell and use it to make copies of itself, which eventually can damage or kill the host cell, and, potentially, the host organism. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge

or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 26 and therefore deny the allegations.

27. Although vaccines targeting viruses may have varying mechanisms of action, they traditionally work by injecting into the body a weakened or inactive form of the virus that is unable to cause infection but retains features of the infectious virus and can teach the immune system to recognize and attack the infectious virus if it invades in the future. These vaccines take tremendous amounts of time to develop and bring to patients due to the extensive amount of work needed to target specific infectious agents, associated regulatory hurdles, and other factors.

RESPONSE: Defendants admit that some vaccines work by injecting into the body a weakened or inactive form of the virus. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 27 and therefore deny the allegations.

28. In a 2021 essay, Pfizer's CEO observed that "the typical vaccine development program can take up to 10 years and cost anywhere from $1 billion to more than $2 billion," including because "[t]raditionally, making a vaccine starts with growing weakened forms of the virus, which can take months."[5]

RESPONSE: To the extent the allegations of Paragraph 28 purport to rely on a public statement, that statement speaks for itself. Defendants deny the remaining allegations of Paragraph 28.

29. Thus, scientists began experimenting with a new, mRNA-based approach. Fundamentally, the proposed mRNA vaccines would work the same way as any other vaccine—exposing people to a piece of a virus or pathogen so as to trigger the immune system and induce adaptive immunity. However, with an mRNA vaccine, the immune system would not be triggered by a piece of virus or pathogen manufactured in a laboratory, as with older vaccines. Instead, the trigger would be manufactured in and by a person's own cells.

[5] Albert Bourla, *The CEO of Pfizer on Developing a Vaccine in Record Time*, Harvard Bus. Rev. Magazine, May-June 2021 (https://hbr.org/2021/05/the-ceo-of-pfizer-on-developing-a-vaccine-in-record-time).

RESPONSE: At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 29 and therefore deny the allegations.

30. A major advantage of mRNA-based vaccines, if they could be made to work, was that they could be used with any mRNA. Rather than requiring years of development as with traditional vaccines, it was envisioned that the relevant mRNA could be identified and generated using existing technology, inserted into a general-use delivery mechanism, and made ready to inject into people, all in the space of days or weeks.

RESPONSE: At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 30 and therefore deny the allegations.

C. Challenges for RNA-Based Medicines and Arbutus's Pioneering Solutions

31. Vaccines and other medicines using RNA technologies are an emerging frontier with the potential to revolutionize medicine. RNA-based medicines can employ a type of RNA called small interfering RNA ("siRNA") to treat certain diseases by interfering with the expression of unwanted proteins to reduce the amounts produced—a process called RNA interference ("RNAi"). RNA-based medicines also can employ mRNA to cause or increase the production of certain proteins. mRNA vaccines, for example, can cause cells to express a protein (or a piece of a protein) that is part of a particular virus or that is found on a particular tumor. The presence of that protein (or piece of a protein) teaches the body's immune system to recognize it if it is encountered in the future and destroy it.

RESPONSE: Defendants admit that siRNA is a type of RNA that may interfere with the expression of certain proteins, and mRNA is a type of RNA that may cause the production of certain proteins. Defendants also admit that mRNA vaccines, if successful, can cause cells to express a protein or a piece of a protein. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 31 and therefore deny the allegations.

32. RNA-based medicines hold great promise for addressing many previously intractable diseases, including viruses like COVID-19 that cause or threaten global pandemics.

RESPONSE: At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 32 and therefore deny the allegations.

33. Despite their promise, however, RNA-based medicines were difficult to develop. By their nature, RNA molecules are fragile. Without adequate protection, RNA molecules are susceptible to degradation in the body; moreover, if and when RNA molecules get to a cell, they cannot cross the cell membrane to enter the cell.

RESPONSE: At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 33 and therefore deny the allegations.

34. For decades, the need for an effective delivery technology had been the most significant challenge in the development of RNA-based medicines. In particular, without the means to protect mRNA and facilitate its entry into target cells, mRNA-based vaccines and other medicines have been ineffective.

RESPONSE: At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 34 and therefore deny the allegations.

35. Dr. Katalin Karikó, former BioNTech Senior Vice President and lead vaccine development scientist, was among the scientists who recognized the significance of the delivery problem. One author quotes Dr. Karikó, speaking in regard to an unsuccessful effort in the years after 2005 to obtain lipids that she believed might be useful in delivering mRNA to human cells, as follows: "I was close to getting on my knees…. It was my lowest moment."[6]

RESPONSE: Defendants admit that Dr. Katalin Karikó is a former BioNTech Senior Vice President. To the extent the allegations of Paragraph 35 purport to rely on a statement from a publication, that statement speaks for itself. Defendants deny the remaining allegations of Paragraph 35.

36. For a long time, the "delivery problem" appeared unsolvable. Indeed, although nucleic acid vaccine development had initially attracted optimism, enthusiasm, and research

[6] Gregory Zuckerman, A SHOT TO SAVE THE WORLD (2021) at 82.

funding, those trends reversed. As explained in a feature in *Nature*, "in the 1990s and for most of the 2000s, nearly every vaccine company that considered working on mRNA opted to invest its resources elsewhere," because "mRNA was seen as too unstable and expensive to be used as a drug or a vaccine."[7] Companies that abandoned the field included one of the world's largest vaccine developers, which according to the same feature in Nature "evaluated the mRNA technology in mice with the aim of creating an influenza vaccine, but then abandoned that approach" because, in the words of a scientist who worked on the project, "'[t]he cost and feasibility of manufacturing just gave us pause.'" As another industry participant explained, "[t]here were many, many skeptics…. People used to say that if you looked at [mRNA] wrong it would fall apart."[8]

RESPONSE: To the extent the allegations of Paragraph 36 purport to rely on public statements, those statements speak for themselves. Defendants deny the remaining allegations of Paragraph 36.

37. Functional RNA-based medicines eluded researchers until pioneering work by Arbutus scientists resulted in the discovery and development of the leading nucleic acid delivery technology in use today. Decades ago, a group of ambitious research scientists working at a predecessor company to Arbutus began to tackle the nucleic acid delivery problems that had long stymied the field. After years of tireless effort, these scientists solved these problems by developing both novel lipid formulations and innovative manufacturing processes. These scientists developed LNP technology that relies on fat-like molecules called lipids that encapsulate and protect nucleic acids like mRNA from degradation in the body and enable them to cross cell membranes. Once inside a cell, the LNP releases the nucleic acid it encapsulates so that, in the case of an mRNA vaccine for example, the nucleic acid can cause the cell to express the protein that the nucleic acid encodes.

RESPONSE: At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 37 and therefore deny the allegations.

38. The lipid components of the Arbutus technology include: structural lipids, such as phospholipids and cholesterol; "cationic" (positive charge-bearing) lipids, including "ionizable" lipids that are positive charge-bearing at certain pH levels; and conjugated lipids, such as lipids attached to a polyethyleneglycol ("PEG") polymer. Arbutus scientists discovered that nucleic acid-

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[7] Elie Dolgin, *The Tangled History Of mRNA Vaccines*, Nature, Sept. 14, 2021 (https://www.nature.com/articles/d41586-021-02483-w).

[8] Ryan Cross, *Without These Lipid Shells, There Would Be No mRNA Vaccines For COVID-19,* Chem. & Engineering News, Mar. 6, 2021 (https://cen.acs.org/pharmaceuticals/drug-delivery/Without-lipid-shells-mRNA-vaccines/99/i8).

lipid particles combining particular lipid components could achieve much more effective delivery of nucleic acids through cell membranes and into cells.

RESPONSE: At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 38 and therefore deny the allegations.

39. Arbutus scientists spent almost two decades researching and developing their nucleic acid-lipid delivery technology. Their efforts led to the first FDA-approved RNA-LNP therapeutic, a drug called Onpattro®. Onpattro® is an RNAi treatment for a form of amyloidosis, a rare disease that causes certain proteins to accumulate in organs. The company that developed Onpattro®, Alnylam Pharmaceuticals, did so under an LNP license from Arbutus and received FDA approval in August 2018. Building on that success, Arbutus has licensed its LNP technology to other companies, and Genevant now has several ongoing LNP product development collaborations, some directed to COVID-19 and some directed to other diseases and disorders.

RESPONSE: Defendants admit that Alnylam markets Onpattro®, which is not an mRNA vaccine. Defendants also admit that the FDA approved Onpattro® in August 2018 for the treatment of polyneuropathy, which is caused by a form of amyloidosis. At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 39 and therefore deny the allegations.

D. The United States Awards Patents Recognizing Arbutus's Innovations

40. In recognition of Arbutus's research and development efforts, the United States Patent and Trademark Office has granted several families of patents claiming nucleic acid-lipid particles and lipid vesicles, as well as compositions and methods of using and manufacturing them. Among those patents are the Asserted Patents:

a. U.S. Patent No. 9,504,651, "Lipid Compositions for Nucleic Acid Delivery," issued on November 29, 2016 (the "'651 Patent").
b. U.S. Patent No. 8,492,359, "Lipid Formulations for Nucleic Acid Delivery," issued on July 23, 2013 (the "'359 Patent").
c. U.S. Patent No. 11,141,378, "Lipid Formulations for Nucleic Acid Delivery," issued on October 12, 2021 (the "'378 Patent").
d. U.S. Patent No. 11,298,320, "Liposomal Apparatus and Manufacturing Methods," issued on April 12, 2022 (the "'320 Patent").

e. U.S. Patent No. 11,318,098, "Liposomal Apparatus and Manufacturing Methods," issued on May 3, 2022 (the "'098 Patent").

RESPONSE: Defendants admit that the Patent and Trademark Office issued the '651 Patent, '359 Patent, '378 Patent, '320 Patent, and '098 Patent, but deny that the Asserted Patents are valid or infringed by Defendants, or that the granting of the Asserted Patents was a "recognition of Arbutus's research and development efforts" or "innovations." Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 40 and therefore deny the allegations.

41. True and correct copies of the Asserted Patents are attached hereto as Exhibits A through E. All are valid and enforceable under United States patent laws. All are assigned to and owned by Arbutus, and, at all times since Arbutus and Genevant entered into a license agreement, Genevant has held Exclusive Rights to all of the Asserted Patents.

RESPONSE: Defendants admit the Exhibits A through E purport to be copies of the Asserted Patents, but deny that the Asserted Patents are valid and enforceable. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 41 and therefore deny the allegations.

E. Defendants' Knowledge Of, And Background With, Arbutus's Patents

42. Defendants have been on actual notice of Arbutus's patents but nonetheless knowingly used Arbutus's technology in nucleic acid-based products and product candidates, including the Accused Product, without permission.

RESPONSE: Paragraph 42 states a legal conclusion to which no response is required. To the extent a response is required, Defendants admit that the Asserted Patents were issued, but deny that the Asserted Patents are valid or infringed by Defendants. Defendants also admit that Plaintiffs sent a letter to Pfizer copying BioNTech on November 23, 2020 identifying the '651 Patent and the '359 Patent. Defendants also admit that Plaintiffs sent a letter to Pfizer copying BioNTech on October 12, 2021 identifying the '378 Patent. Defendants also admit that Genevant

sent email correspondence to BioNTech copying Pfizer on June 3, 2022 identifying the '320 Patent and the '098 Patent. Defendants deny the remaining allegations of Paragraph 42.

43. For example, on July 4, 2018, BioNTech signed a license agreement with Genevant in which BioNTech agreed to pay for the right to use Plaintiffs' LNP technology to develop and potentially commercialize certain cancer or rare liver disease treatments. The first page of the agreement confirms how critical Plaintiffs' LNP technology was: It not only notes Genevant's exclusive license "to certain intellectual property rights relating to RNA-based therapeutics enabled by lipid nanoparticle delivery technologies," but also states that "the Parties wish to jointly develop pharmaceutical products that combine the best mRNA payloads with ***the best lipid nanoparticle technology***"—a reference to Arbutus's technology.

RESPONSE: Defendants admit that there is a license agreement between BioNTech and Genevant, which speaks for itself. Defendants otherwise deny the allegations of Paragraph 43.

44. The license agreement shows, among other things, that BioNTech knew about Arbutus's technology and patents, including the asserted '651 and '359 patents, at least as of 2018. It also shows that BioNTech knew it could not use Arbutus's technology without obtaining and paying for the right to do so. Indeed, BioNTech's annual reports for 2019, 2020, and 2021 referred to "many issued and pending patent filings that claim aspects of technologies that we may need for our mRNA product candidates or other product candidates, ***including patent filings that relate to relevant delivery technologies***." On information and belief, that warning referred at least in part to patents at issue in this litigation.

RESPONSE: Defendants admit that there is a license agreement between BioNTech and Genevant, which speaks for itself. To the extent the allegations of Paragraph 44 purport to rely on annual reports, those reports speak for themselves. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. Defendants otherwise deny the allegations of Paragraph 44.

45. On information and belief, Pfizer has received and reviewed a copy of the BioNTech-Genevant license agreement, including potentially (i) in the summer of 2018, as part of due diligence Pfizer conducted before signing a different contract with BioNTech, and (ii) in early 2020, as part of due diligence Pfizer conducted before agreeing to collaborate with BioNTech on Defendants' vaccine.

RESPONSE: Defendants admit that there is a license agreement between BioNTech and Genevant, which speaks for itself. Defendants deny infringement of any valid claim of the

Asserted Patents and that Plaintiffs are entitled to damages. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 45 and therefore deny the allegations.

F. BioNTech Designs Its COVID-19 Vaccine with Unprecedented Speed, Aided by the Unauthorized Use of Arbutus's LNP Technology

46. Defendants have used and continue to use Arbutus's LNP technology without authority or license to do so and are willfully infringing the Asserted Patents jointly and/or as agents of one another.

RESPONSE: Defendants deny the allegations of Paragraph 46.

47. On January 10, 2020, with the novel SARS-CoV-2 virus quickly spreading around the world, scientists identified the virus's complete genetic sequence and posted it on the internet. This public disclosure revealed the complete RNA sequence that encodes the virus's components, including its distinctive "spike protein." With that information in the public domain, researchers around the world were able to begin designing vaccines to target the virus.

RESPONSE: Defendants admit that the genetic sequence of SARS-CoV-2 was identified and publicly disclosed on January 10, 2020. At least because of the scope, breadth, and vagueness of this allegation, Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 47 and therefore deny the allegations.

48. On Friday, January 24, 2020, BioNTech's CEO read an article about the public health risks posed by COVID-19. According to statements he has given to the press, it was the first time he had focused on COVID-19 as a serious public health threat. ***Over the weekend, he designed several candidates for an mRNA vaccine***, targeting the virus that causes COVID-19 using the RNA sequence that had been published on the internet two weeks earlier. One of those candidates, designed to be inserted into a lipid nanoparticle for delivery into target cells, ultimately became used in Defendants' vaccine. The vaccine was well on its way to clinical trials by the time of the first confirmed American death from COVID-19 in early February 2020.

RESPONSE: The allegations of Paragraph 48 purport to rely on a public statement, but because Paragraph 48 does not cite to a document from which the quote originated, Defendants

lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 48. Defendants deny any remaining allegations of Paragraph 48.

49. Defendants' vaccine could not have been developed, much less on the fastest timeline in the history of vaccines, without Arbutus's proven and patented LNP delivery technology. Indeed, discussing Defendants' vaccine, Dr. Karikó has publicly stated that "***[t]he LNP is as important as the mRNA in the vaccine***."[9] Dr. Karikó has also been quoted as saying that "***a lot of credit goes to [Arbutus scientist and named inventor] Ian MacLachlan for the LNP***" used in the vaccine.[10]

RESPONSE: To the extent the allegations of Paragraph 49 purport to rely on public statements, those statements speak for themselves. Defendants deny the remaining allegations of Paragraph 49.

50. Distribution and administration of the vaccine to persons in the United States and around the world (outside of clinical trials) began immediately after December 11, 2020, when the FDA granted Defendants an Emergency Use Authorization, and has continued through and after the FDA's August 23, 2021 approval to administer the vaccine to persons ages 16 and over.

RESPONSE: Defendants admit that on December 11, 2020, the FDA granted an EUA for Defendants' vaccine and distribution of the vaccine began thereafter. Defendants also admit that the FDA approved the BLA for Comirnaty® on August 23, 2021. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 50 and therefore deny the allegations.

51. Pfizer has asserted that it manufactured more than three billion doses of the vaccine in 2021 and expected to manufacture billions more doses by the end of 2022.[11] Pfizer also reported

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[9] Katalin Karikó (@kkariko), Twitter (Aug. 17, 2021, 10:24 AM) (https://twitter.com/kkariko/status/1427637506913284101?ref_src=twsrc%5Etfw).

[10] Nathan Vardi, *Covid's Forgotten Hero: The Untold Story Of The Scientist Whose Breakthrough Made The Vaccines Possible*, Forbes, Aug. 17, 2021 (https://tinyurl.com/86ud83kj).

[11] Complaint, *BioNTech SE, BioNTech Manuf. GMBH, & Pfizer Inc. v. Curevac AG*, Case No. 1:22-cv-11202 (D. Mass. July 25, 2022) at ¶ 63.

tens of billions in revenue from the vaccine in both 2021 and 2022.[12] Moreover, Pfizer's CEO Dr. Bourla has stated that those revenues actually ***understate*** what a "fair financial return" on the vaccine would have been, including because Pfizer had set prices at a level intended to increase the value of Pfizer's public reputation.[13]

RESPONSE: To the extent the allegations of Paragraph 51 purport to rely on the Complaint filed on July 25, 2022 in *BioNTech SE v. CureVac AG*, No. 22-11202 (D. Mass.), since transferred as *BioNTech SE v. CureVac AG*, No. 23-222 (E.D. Va.), Pfizer's 2022 annual report, and other public statements, those statements speak for themselves. Defendants deny the remaining allegations of Paragraph 51.

52. To date, hundreds of millions of doses of Defendants' vaccine have been administered to individuals throughout the United States.[14] Defendants' vaccine doses made in the United States and/or administered in the United States were distributed to hospitals, pharmacies, clinics, and numerous other entities for the benefit of individuals in the United States.

RESPONSE: Defendants admit that Comirnaty® has been administered in the United States. To the extent the allegations of Paragraph 52 also purport to rely on a publicly available website, that website speaks for itself. Defendants otherwise deny the remaining allegations of Paragraph 52.

53. Millions more doses, including doses made in the United States, have been distributed and administered abroad, for the benefit of individuals outside the United States. In press releases and financial disclosures, Pfizer has stated that it shipped billions of doses to 181 countries. Several of those countries have confirmed that they received doses manufactured in the United States, including Canada, Mexico, and Australia. Moreover, reports indicate that Pfizer has also shipped U.S.-manufactured doses throughout Central and South America.

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[12] Pfizer 10K 2022 Annual Report (https://s28.q4cdn.com/781576035/files/doc_financials/2022/ar/PFE-2022-Form-10K-FINAL-(without-Exhibits).pdf).

[13] Albert Bourla, *MOONSHOT: INSIDE PFIZER'S NINE-MONTH RACE TO MAKE THE IMPOSSIBLE POSSIBLE* (2022) at 108.

[14] COVID-19 Vaccinations in the United States, CDC (https://covid.cdc.gov/covid-data-tracker/#vaccinations_vacc-total-admin-rate-total).

RESPONSE: Defendants admit that doses of Comirnaty® have been made in the United States. The allegations of Paragraph 53 also purport to rely on reports and statements from other countries, but because Paragraph 53 does not cite to a document from which the information originated, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 53. Defendants deny any remaining allegations of Paragraph 53.

G. Genevant Attempts to Negotiate a License with Defendants

54. Plaintiffs tried to avoid the need to file this lawsuit.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 54 and therefore deny the allegations.

55. Many companies have paid Plaintiffs for a license to use the breakthrough LNP technology at issue here, including several developing COVID-19 vaccines and several others with which Genevant has ongoing LNP product development collaborations. The research and development facilitated by these and other licenses has resulted in product candidates across a variety of conditions.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 55 and therefore deny the allegations.

56. Genevant would have preferred to resolve Plaintiffs' dispute with Defendants with a mutually acceptable license. And Genevant has long sought to do just that. In proposing such a license, Genevant did not wish to minimize the importance of Defendants' extensive efforts to manufacture and distribute billions of doses of the vaccine in the midst of a global pandemic. Those efforts have been vitally important and have saved countless lives. Rather, Genevant sought only the fair and reasonable compensation to which Plaintiffs are entitled by law for their contributions to the vaccine—contributions that were the product of decades of pioneering work by Arbutus scientists, many now at Genevant companies, including during periods when it was uncertain whether mRNA vaccines could ultimately be made to work.

RESPONSE: Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. Defendants otherwise lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 56 and therefore deny the allegations.

57. On November 23, 2020, Plaintiffs notified Defendants in writing that the manufacture, importation, offer for sale, sale, and/or use of the Accused Product may infringe the claims of at least the '651 Patent and the '359 Patent and offered to discuss the terms of a collaboration and/or license to further the parties' goal of ending the COVID-19 pandemic. The letter emphasized that Plaintiffs' priority was for COVID-19 to be eradicated and assured that "we do not intend to file a case asserting patent infringement in the near future" to ensure vaccine development efforts were in no way impacted.

RESPONSE: To the extent the allegations of Paragraph 57 purport to rely on a statement from a document sent by Plaintiffs to Pfizer copying BioNTech, that statement speaks for itself. Defendants admit that Plaintiffs sent a letter to Pfizer copying BioNTech on November 23, 2020 identifying the '651 Patent and the '359 Patent. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. Defendants otherwise deny the allegations of Paragraph 57.

58. Although Pfizer responded a month later stating that it would "reach out in due course," it did not do so, and Genevant did not press the matter at that time in deference to Defendants' important efforts to manufacture and distribute the vaccine. However, having heard nothing for over six months, and with global conditions somewhat improved, Genevant reached out orally and in writing multiple times in the second half of 2021 in an effort to initiate a good faith discussion.

RESPONSE: To the extent the allegations of Paragraph 58 purport to rely on a statement from a document sent by Pfizer to Plaintiffs, that statement speaks for itself. Defendants admit that Pfizer responded on December 23, 2020 to Plaintiffs' letter. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. Defendants otherwise deny the allegations of Paragraph 58.

59. On October 12, 2021, Plaintiffs notified Defendants in writing that, in addition to the patents identified in Plaintiffs' November 23, 2020 letter, the manufacture, importation, offer for sale, sale, and/or use of the Accused Product may also infringe the claims of the '378 Patent, which had issued that same day.

RESPONSE: To the extent the allegations of Paragraph 59 purport to rely on a statement from a document sent to Pfizer copying BioNTech by Plaintiffs, that statement speaks for itself.

Defendants admit that Plaintiffs sent a letter to Pfizer copying BioNTech on October 12, 2021 identifying the '378 Patent, which had issued that same day. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. Defendants otherwise deny the allegations of Paragraph 59.

60. On June 3, 2022, Genevant notified Defendants in writing that the manufacture, importation, offer for sale, sale, and/or use of the Accused Product may also infringe the '320 patent, which had issued on April 12, 2022, and the '098 patent, which had issued on May 3, 2022.

RESPONSE: To the extent the allegations of Paragraph 60 purport to rely on a statement from a document sent by Genevant to BioNTech copying Pfizer, that statement speaks for itself. Defendants admit that Genevant sent an email to BioNTech copying Pfizer on June 3, 2022 identifying the '320 Patent, which had issued on April 12, 2022, and the '098 Patent, which had issued on May 3, 2022. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. Defendants otherwise deny the allegations of Paragraph 60.

H. Defendants Refuse to Compensate Plaintiffs for Using Their Technology

61. Despite Genevant's repeated efforts to discuss reasonable terms for a license, Defendants have refused to take a license from, partner with, or otherwise compensate Plaintiffs for their contribution to Defendants' vaccine. Defendants have also declined to provide product samples to support any assertion that they have not infringed the Asserted Patents. Instead, Defendants continue to infringe the Asserted Patents directly and indirectly, without authority and with actual knowledge of, or willfully blind to, the fact that their actions constitute infringement of the Asserted Patents. On information and belief, Pfizer and BioNTech have at all relevant times been working jointly to coordinate their positions and responses on these matters.

RESPONSE: Paragraph 61 states legal conclusions to which no response is required. To the extent a response is required, Defendants admit that Defendants did not provide product samples to Genevant. Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. Defendants otherwise deny the remaining allegations of Paragraph 61.

62. Plaintiffs fully support Defendants' efforts to supply vaccines to people in the United States and worldwide and in no way seek to interfere with those efforts. However, Defendants have made extensive use of, and earned billions of dollars in profit exploiting, Arbutus's patented technology, including the technology described and claimed in the Asserted Patents. Defendants' actions have caused harm, and continue to cause harm, to Plaintiffs. Plaintiffs thus have no choice but to defend their proprietary and patented technology and to seek fair and reasonable compensation for the value of their innovation.[15]

RESPONSE: Defendants deny infringement of any valid claim of the Asserted Patents and that Plaintiffs are entitled to damages. At least because of the scope, breadth, and vagueness of this allegation, Defendants lack the knowledge or information sufficient to form a belief as to the truth of the remaining allegations of Paragraph 62 and therefore deny the allegations.

COUNT 1: INFRINGEMENT OF U.S. PATENT NO. 9,504,651

63. Paragraphs 1 through 62 are incorporated by reference as if fully set forth herein.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 62.

64. The United States Patent and Trademark Office duly and legally issued the '651 Patent to one of Arbutus's predecessor companies on November 29, 2016. The '651 Patent is titled "Lipid Compositions for Nucleic Acid Delivery."

RESPONSE: Defendants admit that the United States Patent and Trademark Office issued U.S. Pat. No. 9,504,651 entitled "Lipid Compositions for Nucleic Acid Delivery" to Protiva Biotherapeutics on November 29, 2016, but deny that the patent is valid or infringed by Defendants. Defendants deny any remaining allegations of Paragraph 64.

65. Arbutus owns, and at all relevant times has owned, the '651 Patent.

[15] The allegations herein are exemplary and without prejudice to Plaintiffs' infringement contentions. In providing these allegations, Plaintiffs do not convey or imply any particular claim constructions or the precise scope of the claims. Plaintiffs' claim construction contentions regarding the meaning and scope of the claim terms will be provided under the Court's scheduling order and this District's Local Civil and Patent Rules.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 65 and therefore deny the allegations.

66. Genevant holds, and at all relevant times has held, Exclusive Rights in the '651 Patent, including the right to sue and seek damages for the infringement alleged herein.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 66 and therefore deny the allegations.

67. Claims of the '651 Patent cover, among other things, lipid vesicle formulations comprising a plurality of lipid vesicles with mRNA encapsulated in the vesicles.

RESPONSE: Paragraph 67 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 67.

68. The FDA's December 11, 2020 Emergency Use Authorization letter to Pfizer ("FDA EUA Letter") indicates that the Accused Product contains a nucleoside-modified mRNA encoding the viral spike protein of SARS-CoV-2. The mRNA is encapsulated in lipid particles comprising the following lipids: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol.

RESPONSE: Paragraph 68 references a letter which speaks for itself and requires no response. To the extent a response is required, Defendants admit that on December 11, 2020, the FDA granted an EUA for Defendants' vaccine, and the EUA letter speaks for itself. Defendants deny any remaining allegations of Paragraph 68.

69. Defendants have directly infringed and continue to directly infringe the claims of the '651 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, and/or using within the United States, and/or importing into the United States, the Accused Product, incorporating Arbutus's LNP delivery technology covered by the '651 Patent, without authority or license to do so, during the term of the '651 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 69.

70. For example, Claim 1 of the '651 Patent recites a "lipid vesicle formulation comprising: (a) a plurality of lipid vesicles, wherein each lipid vesicle comprises: a cationic lipid; an amphipathic lipid; and a polyethyleneglycol (PEG)-lipid; and (b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles."

Claim 9 of the '651 Patent recites "[t]he lipid vesicle formulation of claim 1, wherein each lipid vesicle is a lipid-nucleic acid particle."

RESPONSE: Defendants admit that Claim 1 of the '651 Patent recites "[a] lipid vesicle formulation comprising: (a) a plurality of lipid vesicles, wherein each lipid vesicle comprises: a cationic lipid; an amphipathic lipid; and a polyethyleneglycol (PEG)-lipid; and (b) messenger RNA (mRNA), wherein at least 70% of the mRNA in the formulation is fully encapsulated in the lipid vesicles." Defendants also admit that Claim 9 of the '651 Patent recites "[t]he lipid vesicle formulation of claim 1, wherein each lipid vesicle is a lipid-nucleic acid particle." Defendants deny that the patent is valid or infringed by Defendants.

71. The Accused Product is a lipid vesicle formulation comprising mRNA and lipid vesicles. The mRNA in the Accused Product encodes the COVID-19 spike protein.

RESPONSE: Paragraph 71 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 71.

72. The Accused Product comprises a plurality of lipid vesicles wherein each vesicle comprises the following lipids: an ionizable cationic lipid (((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)); an amphipathic lipid (1,2-distearoyl-sn-glycero-3-phosphocholine or "DSPC"); a PEG-lipid (2[(polyethylene glycol)-2000]-N,N ditetradecylacetamide), and cholesterol.

RESPONSE: Paragraph 72 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 72.

73. Upon information and belief, the Accused Product comprises a lipid vesicle formulation wherein at least 70% of the mRNA in the formulation is fully encapsulated in a plurality of lipid vesicles meeting the requirements of claim 1 of the '651 patent.

RESPONSE: Paragraph 73 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 73.

74. Defendants have also actively induced infringement of one or more claims of the '651 Patent under 35 U.S.C. § 271(b) because: (i) others, including healthcare professionals, have used the Accused Product by administering it to millions of individuals in the United States, thereby directly infringing one or more claims of the '651 Patent; (ii) Defendants have actively

encouraged such other persons, including healthcare professionals, to use the Accused Product by administering it to individuals in the United States; (iii) Defendants intended to cause the directly infringing acts via their active encouragement and such active encouragement has actually led to the directly infringing acts; and (iv) Defendants, when they committed such acts of encouragement, were aware of the '651 patent and knew that use and administration of the Accused Product would, if performed, infringe one or more claims of the '651 patent. Defendants' acts of inducement are continuing.

RESPONSE: Defendants deny the allegations of Paragraph 74.

75. On information and belief, Defendants have known of the '651 Patent since before they commenced the infringing conduct or have been willfully blind to its existence and contents since then. Upon information and belief, Defendants have long been aware of and actively monitored Arbutus's patent portfolio. BioNTech has been aware of the '651 patent at least as early as 2018 when it entered into a license agreement with Genevant. Pfizer has been aware of the '651 patent (i) as early as the summer of 2018, on information and belief, by virtue of diligence Pfizer conducted in advance of entering into a separate contract with BioNTech, (ii) in early 2020, on information and belief, as part of due diligence Pfizer conducted before agreeing to collaborate with BioNTech on Defendants' vaccine, and (iii) certainly as of November 23, 2020, upon receipt of Plaintiffs' letter to Albert Bourla, DVM, Ph.D., Chairman and CEO of Pfizer, and Doug Lankler, Esq., EVP and General Counsel of Pfizer, with copy to BioNTech, inviting discussions of a license and partnering opportunity, notifying Defendants that they may be infringing the '651 Patent, and providing notice under 35 U.S.C. § 287(a). Despite such knowledge, Defendants have engaged in the manufacture, offer for sale, sale and/or use of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and induced others to infringe the '651 patent, in violation of Plaintiffs' patent rights.

RESPONSE: Paragraph 75 states a legal conclusion to which no response is required. To the extent a response is required, and to the extent the allegations of Paragraph 75 purport to rely on agreements and correspondence, those agreements and correspondence speak for themselves. Defendants admit that BioNTech has a license agreement with Genevant, which speaks for itself. Defendants admit that Plaintiffs sent a letter to Pfizer copying BioNTech on November 23, 2020 identifying the '651 Patent and the '359 Patent. Defendants otherwise deny the allegations of Paragraph 75.

76. Plaintiffs are entitled to a judgment that Defendants infringe the claims of the '651 Patent by engaging in the manufacture, use, sale, and/or offer for sale of the Accused Product within the United States, and/or the importation of Defendants' vaccine into the United States, and/or by actively inducing others to do the same.

RESPONSE: Defendants deny the allegations of Paragraph 76.

77. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

RESPONSE: Defendants deny the allegations of Paragraph 77.

78. Defendants have undertaken their infringing actions despite knowing that such actions infringed one or more claims of the '651 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the '651 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 78.

79. This is an exceptional case. Plaintiffs are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Defendants' infringement of the '651 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 79.

COUNT 2: INFRINGEMENT OF U.S. PATENT NO. 8,492,359

80. Paragraphs 1 through 79 are incorporated by reference as if fully set forth herein.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 79.

81. The United States Patent and Trademark Office duly and legally issued the '359 Patent to one of Arbutus's predecessor companies on July 23, 2013. The '359 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

RESPONSE: Defendants admit that the United States Patent and Trademark Office issued U.S. Pat. No. 8,492,359 entitled "Lipid Formulations for Nucleic Acid Delivery" to Protiva Biotherapeutics on July 23, 2013, but deny that the patent is valid or infringed by Defendants. Defendants deny any remaining allegations of Paragraph 81.

82. Arbutus owns, and at all relevant times has owned, the '359 Patent.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 82 and therefore deny the allegations.

83. Genevant holds, and at all relevant times has held, Exclusive Rights in the '359 Patent, including the right to sue and seek damages for the infringement alleged herein.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 83 and therefore deny the allegations.

84. Claims of the '359 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

RESPONSE: Paragraph 84 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 84.

85. The FDA EUA Letter indicates that the Accused Product is comprised of nucleic acid-lipid particles. The nucleic acid is a nucleoside-modified mRNA encoding the viral spike protein of SARS-CoV-2. The mRNA is encapsulated in lipid particles comprising the following lipids: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol. The FDA EUA Letter also provides nominal weights for each of the lipid components.

RESPONSE: Defendants admit that on December 11, 2020, the FDA granted an EUA for Defendants' vaccine, and the EUA letter speaks for itself. Defendants deny any remaining allegations of Paragraph 85.

86. Defendants have directly infringed and continue to directly infringe claims of the '359 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, and/or using within the United States, and/or importing into the United States, the Accused Product incorporating Arbutus's LNP delivery technology covered by the '359 Patent, without authority or license to do so, during the term of the '359 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 86.

87. For example, Claim 1 of the '359 Patent recites a "nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle."

RESPONSE: Defendants admit that Claim 1 of the '359 Patent recites "[a] nucleic acid-lipid particle comprising: (a) a nucleic acid; (b) a cationic lipid comprising from 50 mol % to

65 mol % of the total lipid present in the particle; (c) a non-cationic lipid comprising a mixture of a phospholipid and cholesterol or a derivative thereof, wherein the phospholipid comprises from 3 mol % to 15 mol % of the total lipid present in the particle and the cholesterol or derivative thereof comprises from 30 mol % to 40 mol % of the total lipid present in the particle; and (d) a conjugated lipid that inhibits aggregation of particles comprising from 0.5 mol % to 2 mol % of the total lipid present in the particle." Defendants deny that the patent is valid or infringed by Defendants.

88. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

RESPONSE: Paragraph 88 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 88.

89. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: a cationic lipid having a protonatable tertiary amine (((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)); a mixture of the non-cationic lipids phospholipid (1,2-distearoyl-sn-glycero-3-phosphocholine or "DSPC") and cholesterol; and a PEG-lipid conjugate, 2[(polyethylene glycol)-2000]-N,N ditetradecylacetamide, that inhibits aggregation of particles.

RESPONSE: Paragraph 89 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 89.

90. On information and belief, the Accused Product comprises nucleic acid-lipid particles comprising (a) a cationic lipid comprising from 50 mol % to 65 mol % of the total lipid present in the particle; (b) DSPC comprising from 3 mol % to 15 mol % of the total lipid present in the particle; (c) the cholesterol in the amount of 30 mol % to 40 mol % of the total lipid present in the particle; and (c) a PEG-lipid conjugate consisting of from 0.5 mol % to 2 mol % of the total lipid present in the particle.

RESPONSE: Paragraph 90 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 90.

91. Defendants have also actively induced infringement of one or more claims of the '359 Patent under 35 U.S.C. § 271(b) because: (i) others, including healthcare professionals, have

used the Accused Product by administering it to millions of individuals in the United States, thereby directly infringing one or more claims of the '359 Patent, (ii) Defendants have actively encouraged such other persons, including healthcare professionals, to use the Accused Product by administering it to individuals in the United States, (iii) Defendants intended to cause the directly infringing acts via their active encouragement and such active encouragement has actually led to the directly infringing acts, and (iv) Defendants, when they committed such acts of encouragement, were aware of the '359 Patent and knew that use and administration of the Accused Product would, if performed, infringe one or more claims of the '359 Patent. Defendants' acts of inducement are continuing.

RESPONSE: Defendants deny the allegations of Paragraph 91.

92. On information and belief, Defendants have known of the '359 Patent since before they commenced the infringing conduct or have been willfully blind to its existence and contents since then. Upon information and belief, Defendants have long been aware of and actively monitored Arbutus's patent portfolio. BioNTech has been aware of the '359 patent at least as early as 2018 when it entered into a license agreement with Genevant. Pfizer has been aware of the '359 patent (i) as early as the summer of 2018, on information and belief, by virtue of diligence Pfizer conducted in advance of entering into a separate contract with BioNTech, (ii) in early 2020, on information and belief, as part of due diligence Pfizer conducted before agreeing to collaborate with BioNTech on Defendants' vaccine, and (iii) certainly as of November 23, 2020, upon receipt of Plaintiffs' letter to Albert Bourla, DVM, Ph.D., Chairman and CEO of Pfizer, and Doug Lankler, Esq., EVP and General Counsel of Pfizer, with copy to BioNTech, inviting discussions of a license and partnering opportunity, notifying Defendants that they may be infringing the '359 Patent, and providing notice under 35 U.S.C. § 287(a). Despite such knowledge, Defendants have engaged in the manufacture, offer for sale, sale, and/or use of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and induced others to infringe the '359 patent, in violation of Plaintiffs' patent rights.

RESPONSE: Paragraph 92 states a legal conclusion to which no response is required. To the extent a response is required, and to the extent the allegations of Paragraph 92 purport to rely on agreements and correspondence, those agreements and correspondence speak for themselves. Defendants admit that there is a license agreement between BioNTech and Genevant, which speaks for itself. Defendants also admit that Plaintiffs sent a letter to Pfizer copying BioNTech on November 23, 2020 identifying the '651 Patent and the '359 Patent. Defendants otherwise deny the allegations of Paragraph 92.

93. Despite such knowledge, Defendants have engaged in the unlicensed manufacture, offer for sale, sale and/or use of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, in violation of Plaintiffs' patent rights.

RESPONSE: Defendants deny the allegations of Paragraph 93.

94. Plaintiffs are entitled to a judgment that Defendants infringe the claims of the '359 Patent by engaging in the manufacture, use, sale, and/or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same.

RESPONSE: Defendants deny the allegations of Paragraph 94.

95. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

RESPONSE: Defendants deny the allegations of Paragraph 95.

96. Defendants have undertaken their infringing actions despite knowing that such actions infringe one or more claims of the '359 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the '359 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 96.

97. This is an exceptional case. Plaintiffs are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Defendants' infringement of the '359 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 97.

COUNT 3: INFRINGEMENT OF U.S. PATENT NO. 11,141,378

98. Paragraphs 1 through 97 are incorporated by reference as if fully set forth herein.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 97.

99. The United States Patent and Trademark Office duly and legally issued the '378 Patent to Arbutus on October 12, 2021. The '378 Patent is titled "Lipid Formulations for Nucleic Acid Delivery."

RESPONSE: Defendants admit that the United States Patent and Trademark Office issued U.S. Pat. No. 11,141,378 entitled "Lipid Formulations for Nucleic Acid Delivery" to Arbutus Biopharma Corporation on October 12, 2021, but deny that the patent is valid or infringed by Defendants. Defendants deny any remaining allegations of Paragraph 99.

100. Arbutus owns, and at all relevant times has owned, the '378 Patent.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 100 and therefore deny the allegations.

101. Genevant holds, and at all relevant times has held, Exclusive Rights in the '378 Patent, including the right to sue and seek damages for the infringement alleged herein.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 101 and therefore deny the allegations.

102. On the date that the '378 Patent was issued, Plaintiffs sent Defendants written notice that Defendants may be infringing one or more claims of the '378 Patent and noted ongoing licensing discussions.

RESPONSE: Paragraph 102 references a letter which speaks for itself and requires no response. To the extent a response is required, Defendants admit that Plaintiffs sent a letter to Defendants on October 12, 2021 identifying the '378 Patent, which had issued that same day, and mentioning further discussions regarding a potential license. Defendants deny any remaining allegations of Paragraph 102.

103. Claims of the '378 Patent cover, among other things, nucleic acid-lipid particles and compositions thereof.

RESPONSE: Paragraph 103 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 103.

104. The FDA EUA Letter indicates that the Accused Product is comprised of nucleic acid-lipid particles. The nucleic acid is a nucleoside-modified mRNA encoding the viral spike protein of SARS-CoV-2. The mRNA is encapsulated in lipid particles comprising the following lipids: ((4-hydroxybutyl)azanediyl)bis(hexane-6,1-diyl)bis(2-hexyldecanoate), 2[(polyethylene glycol)-2000]-N,N-ditetradecylacetamide, 1,2-distearoyl-sn-glycero-3-phosphocholine, and cholesterol. The FDA EUA Letter also provides nominal weights for each of the lipid components.

RESPONSE: Paragraph 104 references a letter which speaks for itself and requires no response. Defendants deny any remaining allegations of Paragraph 104.

105. Defendants have directly infringed and continue to directly infringe claims of the '378 Patent under 35 U.S.C. § 271(a) by manufacturing, offering to sell, selling, and/or using within the United States, and/or importing into the United States, the Accused Product incorporating Arbutus's LNP delivery technology covered by the '378 Patent, without authority or license to do so, during the term of the '378 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 105.

106. For example, Claim 1 of the '378 Patent recites a "nucleic acid-lipid particle consisting essentially of: (a) an RNA; (b) a cationic lipid having a protonatable tertiary amine; (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the phospholipid consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle."

RESPONSE: Defendants admit that Claim 1 of the '378 Patent recites "[a] nucleic acid-lipid particle consisting essentially of: (a) an RNA; (b) a cationic lipid having a protonatable tertiary amine; (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the phospholipid consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle." Defendants deny that the patent is valid or infringed by Defendants.

107. The Accused Product is a pharmaceutical composition of nucleic acid-lipid particles. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

RESPONSE: Paragraph 107 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 107.

108. The Accused Product comprises nucleic acid-lipid particles comprising the following lipids: a cationic lipid having a protonatable tertiary amine (((4-hydroxybutyl) azanediyl)bis (hexane-6,1-diyl)bis(2-hexyldecanoate)); a mixture of a phospholipid (1,2-distearoyl-sn-glycero-3-phosphocholine or "DSPC") and cholesterol; and a PEG-lipid conjugate, 2[(polyethylene glycol)-2000]-N,N ditetradecylacetamide.

RESPONSE: Paragraph 108 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 108.

109. On information and belief, the Accused Product comprises nucleic acid-lipid particles comprising (a) a cationic lipid having a protonatable tertiary amine; (b) a mixture of a DSPC and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle, wherein the DSPC consists of from 3 mol % to 15 mol % of the total lipid present in the particle; and (c) a PEG-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle.

RESPONSE: Paragraph 109 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 109.

110. Defendants have also actively induced infringement of one or more claims of the '378 Patent under 35 U.S.C. § 271(b) because: (i) others, including healthcare professionals, have used the Accused Product by administering it to millions of individuals in the United States, thereby directly infringing one or more claims of the '378 Patent, (ii) Defendants have actively encouraged such other persons, including healthcare professionals, to use the Accused Product by administering it to individuals in the United States, (iii) Defendants intended to cause the directly infringing acts via their active encouragement and such active encouragement has actually led to the directly infringing acts, and (iv) Defendants, when they committed such acts of encouragement, were aware of the '378 Patent and knew that use and administration of the Accused Product would, if performed, infringe one or more claims of the '378 Patent. Defendants' acts of inducement are continuing.

RESPONSE: Defendants deny the allegations of Paragraph 110.

111. Despite such knowledge, Defendants have engaged in the unlicensed manufacture, offer for sale, sale, and/or use of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, in violation of Plaintiffs' patent rights.

RESPONSE: Defendants deny the allegations of Paragraph 111.

112. Plaintiffs are entitled to a judgment that Defendants infringe the claims of the '378 Patent by engaging in the manufacture, use, sale, and/or offer for sale of the Accused Product within the United States, and/or the importation of the Accused Product into the United States, and/or by actively inducing others to do the same.

RESPONSE: Defendants deny the allegations of Paragraph 112.

113. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

RESPONSE: Defendants deny the allegations of Paragraph 113.

114. Defendants have undertaken their infringing actions despite knowing that such actions infringe one or more claims of the '378 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the '378 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 114.

115. This is an exceptional case. Plaintiffs are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Defendants' infringement of the '378 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 115.

COUNT 4: INFRINGEMENT OF U.S. PATENT NO. 11,298,320

116. Paragraphs 1 through 115 are incorporated by reference as if fully set forth herein.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 115.

117. The United States Patent and Trademark Office duly and legally issued the '320 Patent to Arbutus on April 12, 2022. The '320 Patent is titled "Liposomal Apparatus and Manufacturing Methods."

RESPONSE: Defendants admit that the United States Patent and Trademark Office issued U.S. Pat. No. 11,298,320 entitled "Liposomal Apparatus and Manufacturing Methods" to Arbutus Biopharma Corporation on April 12, 2022, but deny that the patent is valid or infringed by Defendants. Defendants deny any remaining allegations of Paragraph 117.

118. Arbutus owns, and at all relevant times has owned, the '320 Patent.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 118 and therefore deny the allegations.

119. Genevant holds, and at all relevant times has held, Exclusive Rights in the '320 Patent, including the right to sue and seek damages for the infringement alleged herein.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 119 and therefore deny the allegations.

120. Claims of the '320 Patent cover, among other things, an apparatus for producing lipid vesicles encapsulating a nucleic acid within the lipid vesicle.

RESPONSE: Paragraph 120 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 120.

121. Defendants have directly infringed and continue to directly infringe claims of the '320 Patent under 35 U.S.C. § 271(a) by using the patented apparatus covered by the '320 Patent to make the Accused Product in the United States, without authority or license to do so, during the term of the '320 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 121.

122. For example, Claim 1 of the '320 Patent recites "an apparatus for producing a lipid vesicle encapsulating a nucleic acid within the lipid vesicle, the apparatus comprising: a first reservoir containing an aqueous solution including a nucleic acid; a second reservoir containing an organic lipid solution, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v; and a pump mechanism configured to pump the aqueous solution and the organic lipid solution into a mixing chamber at different flow rates relative to each other; wherein the mixing chamber is configured such that the aqueous solution and the organic lipid solution are introduced into the mixing chamber as opposing flows at about 180º relative to each other and mixed within the mixing chamber to instantaneously produce a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution."

RESPONSE: Defendants admit that Claim 1 of the '320 Patent recites "[a]n apparatus for producing a lipid vesicle encapsulating a nucleic acid within the lipid vesicle, the apparatus comprising: a first reservoir containing an aqueous solution including a nucleic acid; a second reservoir containing an organic lipid solution, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v; and a pump mechanism configured to pump the aqueous solution and the organic lipid solution into a mixing chamber at different flow rates relative to each other; wherein the mixing chamber is configured such that the aqueous solution and the organic lipid solution are introduced into the mixing chamber as opposing flows at about 180º relative to each other and mixed within the mixing chamber to instantaneously produce a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution." Defendants deny that the patent is valid or infringed by Defendants.

123. The Accused Product includes a lipid vesicle encapsulating a nucleic acid. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

RESPONSE: Paragraph 123 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 123.

124. The Accused Product is manufactured using an apparatus with: a first reservoir containing an aqueous solution including a nucleic acid; a second reservoir containing an organic lipid solution; a pump mechanism configured to pump the aqueous solution and the organic lipid solution into a mixing chamber at different flow rates relative to each other; and the mixing chamber is configured such that the aqueous solution and the organic lipid solution are introduced into the mixing chamber as opposing flows at about 180º relative to each other and mixed within the mixing chamber to instantaneously produce a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution.

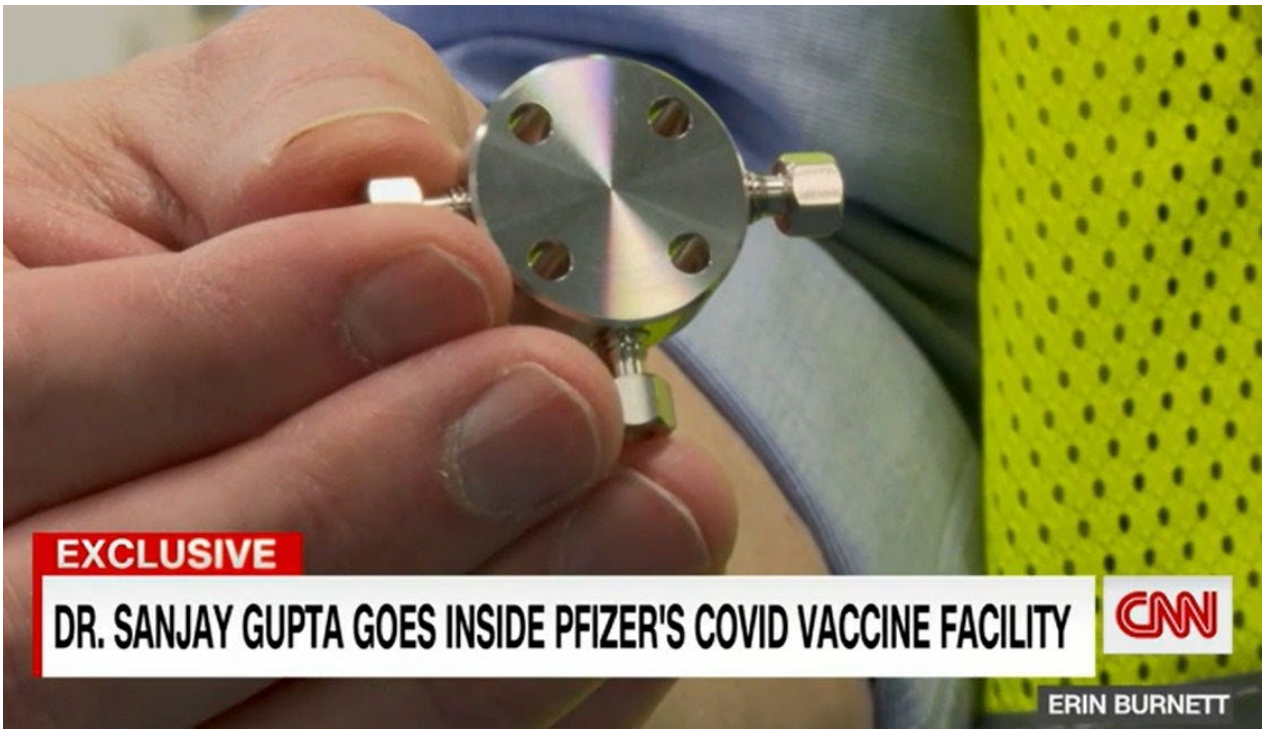
RESPONSE: Paragraph 124 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 124.

125. For example, in his recently published book, Pfizer CEO Dr. Bourla describes the manufacturing of the Accused Product with an apparatus that meets the above-recited limitations. He confirms that the apparatus used to make the Accused Product employs "high pressure pumps" for pumping "aqueous materials" (thus from a first reservoir containing an aqueous solution including a nucleic acid) and "organic streams" (thus from a second reservoir containing an organic lipid solution). Opposing steams of the aqueous solution and the organic solution are mixed in a "T-mixer" with "internal geometry that enables the formation to combine into the lipid nanoparticle." In order to scale production they "replicated the pumps and T-mixers dozens and dozens of times into lipid nanoparticle skids" similar to a "warehouse-sized data center with hundreds and hundreds of racks of network computers," only here with hundreds and hundreds of lipid nanoparticle skids.[16]

RESPONSE: Paragraph 125 states a legal conclusion to which no response is required. To the extent a response is required, and to the extent the allegations of Paragraph 125 purport to rely on public statements, those statements speak for themselves. Defendants otherwise deny the allegations of Paragraph 125.

[16] Albert Bourla, *MOONSHOT: INSIDE PFIZER'S NINE-MONTH RACE TO MAKE THE IMPOSSIBLE POSSIBLE* (2022) at 91.

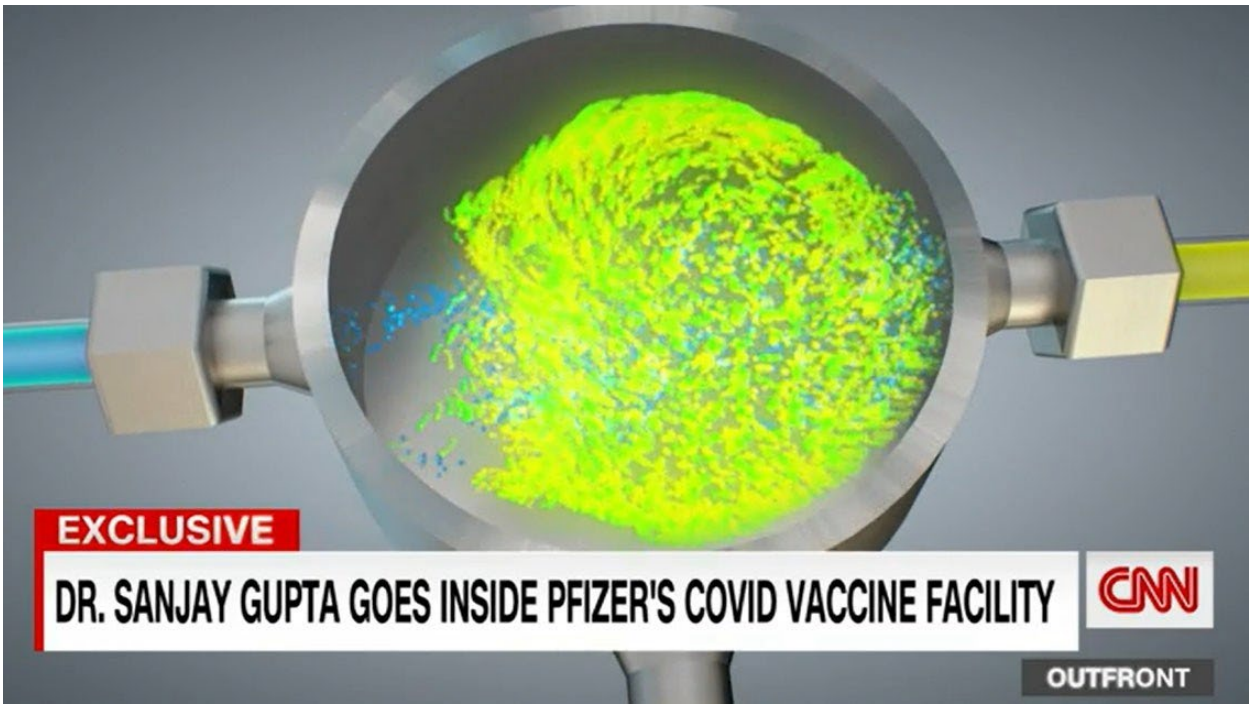
126. On information and belief, the "T-mixer" used in the manufacturing process is shown below. This image is a screen grab from a CNN interview of Mike McDermott, Pfizer's President of Global Supply, during which Mr. McDermott gave a tour of a Pfizer US-based production facility and explained how the T-mixer is used to create LNPs.[17]



RESPONSE: To the extent the allegations of Paragraph 126 purport to rely on a CNN interview, that interview speaks for itself. Defendants otherwise deny the allegations of Paragraph 126.

127. As shown in the below image, also from the CNN interview, the T-mixer is a mixing chamber configured to create opposing flows of the aqueous (blue) and lipid (yellow) solutions at about 180º relative to each other and at different flow rates relative to each other.

[17] CNN, "Take an exclusive look inside a busy Covid-19 vaccine facility"(www.cnn.com/videos/health/2021/03/31/pfizer-vaccine-manufacturing-exclusive-gupta-vpx.cnn).



RESPONSE: Paragraph 127 states a legal conclusion to which no response is required. To the extent a response is required, and to the extent the allegations of Paragraph 127 purport to rely on a CNN interview, that interview speaks for itself. Defendants otherwise deny the allegations of Paragraph 127.

128. On information and belief, the apparatus for making the Accused Product has a second reservoir containing an organic lipid solution wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v.

RESPONSE: Paragraph 128 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 128.

129. The ’320 Patent issued on April 12, 2022. On June 3, 2022, Genevant notified Defendants in writing that the manufacture of the Accused Product may infringe the ’320 Patent.

RESPONSE: To the extent the allegations of Paragraph 129 purport to rely on a statement from a document sent by Genevant to BioNTech copying Pfizer, that statement speaks for itself. Defendants admit that Genevant sent an email to BioNTech copying Pfizer on June 3, 2022

identifying the '320 Patent, which had issued on April 12, 2022. Defendants otherwise deny the remaining allegations of Paragraph 129.

130. Despite such knowledge, Defendants nonetheless have engaged in the manufacture of the Accused Product using an apparatus as claimed in the '320 Patent within the United States, in violation of Plaintiffs' patent rights.

RESPONSE: Defendants deny the allegations of Paragraph 130.

131. Arbutus and Genevant are entitled to a judgment that Defendants infringe the claims of the '320 Patent by engaging in the manufacture, use, sale, and/or offer for sale of the Accused Product within the United States, using an apparatus as claimed in the '320 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 131.

132. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

RESPONSE: Defendants deny the allegations of Paragraph 132.

133. Defendants have undertaken their infringing actions despite knowing that such actions infringe one or more claims of the '320 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the '320 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 133.

134. This is an exceptional case. Plaintiffs are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Defendants' infringement of the '320 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 134.

COUNT 5: INFRINGEMENT OF U.S. PATENT NO. 11,318,098

135. Paragraphs 1 through 134 are incorporated by reference as if fully set forth herein.

RESPONSE: Defendants incorporate by reference their responses contained in Paragraphs 1 through 134.

136. The United States Patent and Trademark Office duly and legally issued the '098 Patent to Arbutus on May 3, 2022. The '098 Patent is titled "Liposomal Apparatus and Manufacturing Methods."

RESPONSE: Defendants admit that the United States Patent and Trademark Office issued U.S. Pat. No. 11,318,098 entitled "Liposomal Apparatus and Manufacturing Methods" to Arbutus Biopharma Corporation on May 3, 2022, but deny that the patent is valid or infringed by Defendants. Defendants deny any remaining allegations of Paragraph 136.

137. Arbutus owns, and at all relevant times has owned, the '098 Patent.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 137 and therefore deny the allegations.

138. Genevant holds, and at all relevant times has held, Exclusive Rights in the '098 Patent, including the right to sue and seek damages for the infringement alleged herein.

RESPONSE: Defendants lack the knowledge or information sufficient to form a belief as to the truth of the allegations of Paragraph 138 and therefore deny the allegations.

139. Claims of the '098 Patent cover, among other things, processes for producing lipid vesicles encapsulating a nucleic acid within the lipid vesicle.

RESPONSE: Paragraph 139 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 139.

140. Defendants have directly infringed and continue to directly infringe claims of the '098 Patent under 35 U.S.C. § 271(a) by manufacturing the Accused Product using the process claimed in one or more claims of the '098 Patent, without authority or license to do so, during the term of the '098 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 140.

141. For example, Claim 1 of the '098 Patent recites "[a] process for producing a lipid vesicle encapsulating a nucleic acid within the lipid vesicle, the process comprising: providing an aqueous solution including a nucleic acid in a first reservoir; providing an organic lipid solution in a second reservoir, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v; introducing the aqueous solution and the organic lipid solution into a mixing chamber as opposing flows at about l80° relative to each other and at different flow rates relative to each other; and mixing the organic lipid solution with the aqueous solution, wherein the mixing instantaneously produces a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution."

RESPONSE: Defendants admit that Claim 1 of the '098 Patent recites "[a] process for producing a lipid vesicle encapsulating a nucleic acid within the lipid vesicle, the process comprising: providing an aqueous solution including a nucleic acid in a first reservoir; providing an organic lipid solution in a second reservoir, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v; introducing the aqueous solution and the organic lipid solution into a mixing chamber as opposing flows at about l80° relative to each other and at different flow rates relative to each other; and mixing the organic lipid solution with the aqueous solution, wherein the mixing instantaneously produces a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution." Defendants deny that the patent is valid or infringed by Defendants.

142. Pfizer, itself and through its subsidiary companies, has performed each step of one or more of the method claims of the '098 Patent in the United States in its manufacturing facilities. Pfizer performs each step of one or more method claims of the '098 Patent in the United States on its own behalf and on behalf of BioNTech.

RESPONSE: Defendants deny the allegations of Paragraph 142.

143. The Accused Product includes a lipid vesicle encapsulating a nucleic acid. The nucleic acid in the Accused Product is an mRNA which encodes the COVID-19 spike protein.

RESPONSE: Paragraph 143 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 143.

144. The Accused Product is manufactured via a process for producing a lipid vesicle encapsulating a nucleic acid within the lipid vesicle, the process comprising: providing an aqueous solution including a nucleic acid in a first reservoir; providing an organic lipid solution in a second reservoir, wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol; introducing the aqueous solution and the organic lipid solution into a mixing chamber as opposing flows at about l80° relative to each other and at different flow rates relative to each other; and mixing the organic lipid solution with the aqueous solution, wherein the mixing instantaneously produces a lipid vesicle encapsulating the nucleic acid within the lipid vesicle by diluting the concentration of the lower alkanol in the organic lipid solution.

RESPONSE: Paragraph 144 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 144.

145. For example, in his recently published book, Pfizer CEO Dr. Bourla describes the Defendants' manufacturing of the Accused Product via a process that meets the above-recited limitations. He confirms that Defendants' "high pressure pumps" that pump "aqueous materials" (thus from a first reservoir containing an aqueous solution including a nucleic acid) and "organic streams" (thus from a second reservoir containing an organic lipid solution). Opposing steams of the aqueous solution and the organic solution are mixed in a "T-mixer" with "internal geometry that enables the formation to combine into the lipid nanoparticle." To scale production, Defendants "replicated the pumps and T-mixers dozens and dozens of times into lipid nanoparticle skids" similar to a "warehouse-sized data center with hundreds and hundreds of racks of network computers," only here with hundreds and hundreds of lipid nanoparticle skids.[18]

RESPONSE: Paragraph 145 states a legal conclusion to which no response is required. To the extent a response is required, and to the extent the allegations of Paragraph 145 purport to rely on public statements, those statements speak for themselves. Defendants otherwise deny the allegations of Paragraph 145.

146. As shown in the images above (*see supra* ¶¶ 126-127), the T-mixer is a mixing chamber used to create opposing flows of the aqueous (blue) and lipid (yellow) solutions at about 180º relative to each other and at different flow rates relative to each other.

RESPONSE: Paragraph 146 states a legal conclusion to which no response is required. To the extent a response is required, and to the extent the allegations of Paragraph 146 purport to rely on a CNN interview, that interview speaks for itself. Defendants otherwise deny the allegations of Paragraph 146.

147. On information and belief, in the process for making the Accused Product Defendants provide a second reservoir containing an organic lipid solution wherein the lipids present in the organic lipid solution are solubilized in a lower alkanol at a concentration of about 75% v/v to 100% v/v.

[18] Albert Bourla, *MOONSHOT: INSIDE PFIZER'S NINE-MONTH RACE TO MAKE THE IMPOSSIBLE POSSIBLE* (2022) at 91.

RESPONSE: Paragraph 147 states a legal conclusion to which no response is required. To the extent a response is required, Defendants deny the allegations of Paragraph 147.

148. The '098 Patent issued on May 3, 2022. On June 3, 2022, Genevant notified Defendants in writing that the manufacture of the Accused Product may infringe the '098 patent.

RESPONSE: To the extent the allegations of Paragraph 148 purport to rely on a statement from a document sent by Genevant to BioNTech copying Pfizer, that statement speaks for itself. Defendants admit that Genevant sent an email to BioNTech copying Pfizer on June 3, 2022 identifying the '098 Patent, which had issued on May 3, 2022. Defendants otherwise deny the remaining allegations of Paragraph 148.

149. Despite such knowledge, Defendants have engaged in the manufacture of the Accused Product via a process as claimed in one or more claims of the '098 Patent within the United States, in violation of Plaintiffs' patent rights.

RESPONSE: Defendants deny the allegations of Paragraph 149.

150. Arbutus and Genevant are entitled to a judgment that Defendants infringe the claims of the '098 Patent by engaging in the manufacture of the Accused Product within the United States.

RESPONSE: Defendants deny the allegations of Paragraph 150.

151. Defendants' infringement has damaged and continues to damage Genevant and Arbutus in an amount yet to be determined, in the form of a reasonable royalty.

RESPONSE: Defendants deny the allegations of Paragraph 151.

152. Defendants have undertaken their infringing actions despite knowing that such actions infringe one or more claims of the '098 Patent. As such, Defendants have and continue to willfully infringe one or more claims of the '098 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 152.

153. This is an exceptional case. Plaintiffs are entitled to attorneys' fees and costs under 35 U.S.C. § 285 as a result of Defendants' infringement of the '098 Patent.

RESPONSE: Defendants deny the allegations of Paragraph 153.

RESPONSE TO PRAYER FOR RELIEF

Defendants deny all allegations not expressly admitted herein. The remainder of Plaintiffs' Complaint is a prayer for relief and does not require a response. To the extent any response is required, Defendants deny that Plaintiffs are entitled to any of the remedies or relief included in Plaintiffs' Prayer for Relief.

JURY DEMAND

Defendants join Plaintiffs' request for a trial by jury on all claims so triable in this action.

AFFIRMATIVE DEFENSES

Further answering the Complaint, Defendants assert the following defenses without assuming any burden that they would not otherwise have, including without admitting or acknowledging that they bear the burden of proof as to any of them. Defendants reserve the right to amend their answer in accordance with the Federal Rules of Civil Procedure and Local Civil Rules of the U.S. District Court for the District of New Jersey to assert additional defenses as further information is obtained.

FIRST AFFIRMATIVE DEFENSE
(NON-INFRINGEMENT OF THE ASSERTED PATENTS)

Defendants have not infringed any valid claim of the Asserted Patents, either directly or indirectly.

SECOND AFFIRMATIVE DEFENSE
(INVALIDITY OF THE ASSERTED PATENTS)

Each and every claim of the Asserted Patents is invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. § 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112, and/or any other judicially created requirements for patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

THIRD AFFIRMATIVE DEFENSE
(PATENT MISUSE)

Plaintiffs have sought to enforce the Asserted Patents for products and acts that Plaintiffs know are outside the claims of the Asserted Patents, rendering the Asserted Patents unenforceable on account of patent misuse.

FOURTH AFFIRMATIVE DEFENSE
(FAILURE TO STATE A CLAIM)

Plaintiffs' Complaint fails to state a claim on which relief can be granted.

FIFTH AFFIRMATIVE DEFENSE
(FAILURE TO JOIN A REQUIRED PARTY)

Plaintiffs' Complaint improperly failed to name or join Acuitas Therapeutics, Inc.

SIXTH AFFIRMATIVE DEFENSE
(NO WILLFUL INFRINGEMENT)

Defendants have not willfully infringed, and do not willfully infringe, any valid claim of any of the Asserted Patents.

SEVENTH AFFIRMATIVE DEFENSE
(NO EXCEPTIONAL CASE)

Defendants' actions in defending this case or otherwise do not give rise to an exceptional case in Plaintiffs' favor under 35 U.S.C. § 285.

EIGHTH AFFIRMATIVE DEFENSE
(PROSECUTION HISTORY DISCLAIMER AND ESTOPPEL)

Plaintiffs are barred, based on statements, representations, and admissions made during prosecution of the patent applications resulting in the Asserted Patents or related patent applications, from asserting any interpretation of any valid claims of the Asserted Patents that would be broad enough to cover any accused product alleged to infringe the Asserted Patents, either literally or by application of the doctrine of equivalents, or under any theory of infringement.

NINTH AFFIRMATIVE DEFENSE
(ESTOPPEL, WAIVER, ACQUIESCENCE, LACHES, AND UNCLEAN HANDS)

Plaintiffs' claims and/or requested relief are barred by one or more of the doctrines of estoppel, waiver, acquiescence, laches, and unclean hands from enforcing or claiming damages with respect to any claim of the Asserted Patents.

TENTH AFFIRMATIVE DEFENSE
(35 U.S.C. § 271(e)(1))

Aspects of Defendants' alleged infringement of the Asserted Patents are reasonably related to Defendants' development and submission of information to the FDA for the Emergency Use Authorization and the Biologics License Application regarding Comirnaty®, and such claims against Defendants are barred by the safe harbor of 35 U.S.C. § 271(e)(1).

ELEVENTH AFFIRMATIVE DEFENSE
(NO COSTS)

Plaintiffs are barred by 35 U.S.C. § 288 from recovering any costs associated with this action.

TWELFTH AFFIRMATIVE DEFENSE
(LIMITATION ON DAMAGES)

Plaintiffs' damages are limited under 35 U.S.C. § 287.

COUNTERCLAIMS

Pursuant to Rule 13 of the Federal Rules of Civil Procedure, Pfizer Inc. ("Pfizer") and BioNTech SE ("BioNTech") (collectively, "Defendants" or "Counterclaimants"), by and through their attorneys, bring the following Counterclaims against Arbutus Biopharma Corp. ("Arbutus") and Genevant Sciences GmbH ("Genevant") (collectively, "Plaintiffs" or "Counterclaim-Defendants"):

1. Counterclaimants on personal knowledge as to their own acts, and on information and belief as to all others based on their own and their attorneys' investigation, and without

admitting the allegations of Plaintiffs other than those expressly admitted herein, bring the following Counterclaims against Arbutus and Genevant for declaratory judgment that United States Patent Nos. 9,504,651 (the "'651 Patent"); 8,492,359 (the "'359 Patent"); 11,141,378 (the "'378 Patent"); 11,298,320 (the "'320 Patent"); and 11,318,098 (the "'098 Patent") (collectively, the "Asserted Patents") are invalid and not infringed by Counterclaimants. Additionally, Counterclaimants bring the following Counterclaims that the '378 Patent, '320 Patent, and '098 Patent are unenforceable.

2. Counterclaimants repeat and incorporate by reference each of the foregoing paragraphs of Defendants' Answer and Affirmative Defenses to the Complaint, as if fully set forth herein.

THE PARTIES

3. Pfizer is a corporation organized and existing under the laws of the State of Delaware, with its principal place of business at 66 Hudson Boulevard, New York, New York 10001.

4. BioNTech is a corporation organized and existing under the laws of Germany with a principal place of business at An der Goldgrube 12, D-55131 Mainz, Germany.

5. According to its Complaint (D.I. 1), Arbutus is a corporation organized and existing under the laws of Canada, with its principal place of business at 701 Veterans Circle, Warminster, Pennsylvania 18974. According to its Complaint, Arbutus is the owner by assignment of the Asserted Patents.

6. According to its Complaint (D.I. 1), Genevant is a corporation organized and existing under the laws of Switzerland, with its principal place of business at Viaduktstrasse 8, 4051 Basel, Switzerland. According to its Complaint, Genevant is the licensee to exclusive rights

for the Asserted Patents to sublicense, practice, and sue for infringement in certain fields of use that allegedly include the vaccine application at issue in its Complaint.

JURISDICTION AND VENUE

7. This Court has subject matter jurisdiction over these Counterclaims for declaratory judgment pursuant to 28 U.S.C. §§ 1331, 1338(a), 2201, and 2202 based on an actual controversy among the parties arising under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.*

8. Personal jurisdiction over Arbutus and Genevant is proper because each has consented to the personal jurisdiction of the Court by commencing their action for patent infringement in this judicial district, as set forth in their Complaint.

9. Venue is proper in this judicial district based on the choice of forum by Arbutus and Genevant and under 28 U.S.C. § 1391(b)-(c).

10. There is an actual justiciable controversy among the parties concerning non-infringement and invalidity of the Asserted Patents.

CASE AND CONTROVERSY

11. The ’651 Patent, titled “Lipid Compositions for Nucleic Acid Delivery,” states an issue date of November 29, 2016 and names as inventors Ian MacLachlan, Lloyd Jeffs, Lorne R. Palmer, and Cory Giesbrecht. Upon information and belief, a true and correct copy of the ’651 Patent is attached to the Complaint as Exhibit A (D.I. 1-1).

12. The ’359 Patent, titled “Lipid Formulations for Nucleic Acid Delivery,” states an issue date of July 23, 2013 and names as inventors Edward Yaworski, Kieu Lam, Lloyd Jeffs, Lorne Palmer, and Ian MacLachlan. Upon information and belief, a true and correct copy of the ’359 Patent is attached to the Complaint as Exhibit B (D.I. 1-2).

13. The ’378 Patent, titled “Lipid Formulations for Nucleic Acid Delivery,” states an issue date of October 12, 2021 and names as inventors Edward Yaworski, Kieu Lam, Lloyd Jeffs,

Lorne Palmer, and Ian MacLachlan. Upon information and belief, a true and correct copy of the '378 Patent is attached to the Complaint as Exhibit C (D.I. 1-3).

14. The '320 Patent, titled "Liposomal Apparatus and Manufacturing Methods," states an issue date of April 12, 2022 and names as inventors Ian MacLachlan, Lloyd B. Jeffs, Lorne R. Palmer, and Cory Giesbrecht. Upon information and belief, a true and correct copy of the '320 Patent is attached to the Complaint as Exhibit D (D.I. 1-4).

15. The '098 Patent, titled "Liposomal Apparatus and Manufacturing Methods," states an issue date of May 3, 2022 and names as inventors Ian MacLachlan, Lloyd B. Jeffs, Lorne R. Palmer, and Cory Giesbrecht. Upon information and belief, a true and correct copy of the '098 Patent is attached to the Complaint as Exhibit E (D.I. 1-5).

16. Arbutus purports to be the owner and assignee of all Asserted Patents.

17. Genevant purports to be an exclusive licensee to all Asserted Patents.

18. An actual, substantial, and justifiable controversy, within the meaning of 28 U.S.C. §§ 2201 and 2202, exists between Counterclaimants and Counterclaim-Defendants.

19. Counterclaimants are entitled to a judicial determination and declaration that they have not infringed and are not infringing the Asserted Patents and that the Asserted Patents are invalid. Counterclaimants additionally seek a declaration that the '378 Patent, '320 Patent, and '098 Patent are unenforceable.

BACKGROUND ON COMIRNATY®

20. In December of 2019, it was discovered that an outbreak of pneumonia among people who had visited the Huanan Seafood Wholesale Market in Wuhan, China was caused by a novel coronavirus, eventually designated by the World Health Organization as SARS-CoV-2 with the disease it causes reclassified as Coronavirus disease 2019 ("COVID-19").

21. COVID-19 quickly spread around the world and tore through populations that were immunologically naïve, threatening the collapse of the healthcare system and the loss of life at scales not seen since the advent of modern medicine. What began first as small area lockdowns to prevent the transmission of disease and temporary stay-at-home orders eventually became society altering restrictions. Many saw that the only path out of the pandemic was the development of successful vaccines against the disease.

22. On January 10, 2020, the Chinese Center for Disease Control published the genetic sequence of SARS-CoV-2.

23. BioNTech scientists had been working in the field of mRNA technology since at least the founding of the company in 2008. BioNTech was working on messenger RNA ("mRNA")-based clinical vaccine candidates by the early- to mid-2010s. BioNTech was earning itself a reputation as an industry leader in mRNA technology.

24. To combat the pandemic, BioNTech scientists set to work on developing a COVID-19 disease vaccine. BioNTech was able to do so by building on its existing development work and experience with mRNA-based clinical vaccine candidates. BioNTech eventually identified a product candidate—then known as BNT162—as a potential mRNA-based vaccine that would protect against COVID-19.

25. In March 2020, Pfizer and BioNTech began a collaborative effort focused on bringing a COVID-19 disease vaccine to market. The vaccine that ultimately emerged from this partnership was a novel mRNA vaccine now known as Comirnaty®.

26. Clinical trials of Pfizer/BioNTech vaccine candidates began in late April of 2020, with preliminary Phase 3 results demonstrating their safety and efficacy published in just over six months.

27. On November 20, 2020, Pfizer, on behalf of itself and BioNTech, submitted its clinical trial data as part of its Emergency Use Authorization ("EUA") request to the Food and Drug Administration ("FDA") for administering its mRNA vaccine to people 16 years of age and older.

28. On December 10, 2020, the FDA granted the first EUA for a COVID-19 vaccine to Pfizer and BioNTech's mRNA vaccine (now known as Comirnaty®) with vaccinations rolling out immediately thereafter, reflecting the fastest development of a vaccine in history.

29. The FDA provided Pfizer and BioNTech's vaccine with full approval on August 23, 2021.

30. Since being granted EUA, millions of doses of Comirnaty® have been administered worldwide, resulting in countless numbers of lives saved while easing the strain of an otherwise uncontrollable pandemic. During this same time, Arbutus and Genevant did not develop or sell any COVID-19 vaccine.

BIONTECH'S RELATIONSHIP WITH ACUITAS

31. Comirnaty® is an mRNA vaccine. For an mRNA vaccine to be effective, the mRNA needs to enter into the cells of the patient. However, mRNA typically breaks down quickly when injected into the body and cannot enter into a patient's cells on its own. An effective mRNA vaccine therefore also requires a delivery system that will protect the mRNA after injection into the patient and transport the mRNA into the patient's cells.

32. The need for a delivery system for a COVID-19 vaccine led BioNTech to partner with Acuitas Therapeutics, Inc. ("Acuitas") in the design of the COVID-19 vaccine lipid nanoparticle formulation. Upon information and belief, Acuitas had painstakingly engineered a microscopic sphere of fats called a lipid nanoparticle ("LNP") that can envelop and protect the

mRNA. These LNPs allow the mRNA to cross the membrane of a human cell and then release the mRNA payload so it can be used to create the proteins that will in turn generate a protective immune response.

33. Acuitas actively participated in the development of Comirnaty®. For example, during the development of Comirnaty®, Acuitas recommended using a lipid composition containing its proprietary lipids ALC-0315 and ALC-0159. Upon information and belief, this lipid composition had been shown to be effective in a prior clinical trial for a rabies vaccine. Acuitas also actively participated in the selection and design of the proportions of LNP components.

34. BioNTech licensed ALC-0315 and ALC-0159 (otherwise known by their IUPAC names [4-hydroxybutyl)azanediyl]di(hexane-6,1-diyl) bis(2-hexyldecanoate), and alpha-[2-(ditetradecylamino)-2-oxoethyl]-omega-methoxy-poly(oxy-1,2-ethanediyl), respectively) from Acuitas.

ONGOING LITIGATION BETWEEN PLAINTIFFS AND ACUITAS

35. On November 23, 2020, days after Pfizer and BioNTech's successful Phase 3 clinical-trial results for Comirnaty® were made public, Arbutus and Genevant sent a demand letter to Pfizer, copying BioNTech, stating: "We believe and notify you as contemplated by 35 U.S.C. § 287(a) that the manufacture, importation, offer for sale, sale, and/or use of your COVID-19 vaccine may infringe Arbutus patents, including at least U.S. Patent Nos. 8,058,069, 8,492,359, 8,822,668, 9,006,417, 9,404,127, 9,364,435, 9,504,651, and 9,518,272."

36. On October 12, 2021, Genevant and Arbutus wrote another letter to Pfizer, copying BioNTech, stating: "[W]e believe, and notify Pfizer and BioNTech under 35 U.S.C. § 287(a), that the manufacture, importation, offer for sale, sale, and/or use of the Pfizer-BioNTech COVID-19

vaccine Comirnaty® may infringe Arbutus U.S. Patent No. 11,141,378, in addition to at least the Arbutus patents that were identified in our November 23, 2020 letter."

37. Genevant and Arbutus identified three of the five patents at issue in this litigation in their November 23, 2020 and October 12, 2021 letters, *i.e.* the '359, '651, and '378 patents. The remaining two patents asserted by Genevant and Arbutus in this litigation had not issued at that time.

38. On March 18, 2022, Acuitas filed an action against Arbutus and Genevant in the U.S. District Court for the Southern District of New York on March 18, 2022, seeking a declaratory judgement that the identified patents were invalid and not infringed. *Acuitas Therapeutics Inc. v. Genevant Sciences GmbH and Arbutus Biopharma Corp.*, No. 22-2229 (S.D.N.Y. Mar. 18, 2022), D.I. 1.

39. On June 3, 2022, Genevant sent email correspondence to BioNTech, copying Pfizer, stating: "We are sending this email to memorialize our disclosure made on [a previous] call of two additional Arbutus patents, U.S. Patent Nos. 11,298,320 and 11,318,098, which we believe, like the patents specified in our November 23, 2020 and October 12, 2021 letters sent to Pfizer and BioNTech, may be infringed by the manufacture, importation, offer to sale, sale, and/or use of the Pfizer-BioNTech COVID-19 vaccine Comirnaty."

40. Following this email correspondence and in response to Acuitas's declaratory judgment action, Arbutus and Genevant filed a motion to dismiss, asserting that there was not in fact a case or controversy. *Acuitas Therapeutics Inc. v. Genevant Sciences GmbH and Arbutus Biopharma Corp.*, No. 22-2229 (S.D.N.Y. Oct. 4, 2022), D.I. 44.

41. In support of their motion to dismiss, Arbutus and Genevant argued that they had not, in fact, ever threatened BioNTech or Pfizer with patent infringement, stating: "The letters

state that Pfizer and BNT 'may' infringe Defendants' patents, which is far short of the types of accusations of infringement that the Federal Circuit has found to create an actual controversy as to infringement." *Id.* at 23.

42. After sending the November 23, 2020 letter, October 12, 2021 letter, and June 3, 2022 email correspondence, Arbutus and Genevant ceased communications with BioNTech and Pfizer, and ten months later, filed their instant patent infringement action in the District of New Jersey. Upon information and belief, Arbutus and Genevant have no reasonable explanation for why they decided to file suit in this district on April 4, 2023, after previously contending that they had not threatened BioNTech or Pfizer with patent infringement.

43. Arbutus and Genevant's motion to dismiss in the Southern District of New York was fully briefed as of November 16, 2022. The Southern District of New York court has not ruled on the motion as of the date of this filing.

44. In their Complaint, Arbutus and Genevant did not identify Acuitas by name. For example, Arbutus and Genevant did not identify the lipids in Comirnaty® by their commonly known Acuitas trade names of ALC-0315 and ALC-0159, but instead only used their lengthy chemical names.

ARBUTUS AND GENEVENT IMPROPERLY SEEK TO PROFIT FROM PFIZER AND BIONTECH'S COMIRNATY® COVID-19 VACCINE

45. On information and belief, Protiva Biotherapeutics Ltd. ("Protiva") was founded in 2000 by Ian MacLachlan, a named inventor on all Asserted Patents.

46. On information and belief, Protiva combined with Tekmira Pharmaceuticals Corp. ("Tekmira") in 2008.

47. On information and belief, Tekmira's founders left Tekmira and eventually formed a new venture, known today as Acuitas, to develop LNP technology. Specifically, Acuitas sought

to develop lipid carriers for delivering mRNA, whereas Tekmira sought to develop lipid carriers for delivering small interfering RNA ("siRNA").

48. On information and belief, Tekmira changed its corporate name to Arbutus Biopharma Corp. in 2015.

49. Arbutus and Genevant, which purports to be an exclusive licensee of all Asserted Patents, have made belated efforts to improperly expand the Arbutus patent portfolio so that they can try to capitalize on Pfizer and BioNTech's success.

50. Arbutus and Genevant now seek to profit not from technology Arbutus or its predecessors invented, but rather from improperly contorting the claims of Arbutus's recent patent applications to what they allege covers Comirnaty®.

51. Arbutus or Genevant do not report having made and used an LNP encapsulating mRNA in any of the Asserted Patents.

52. Arbutus and Genevant's alleged lipid technology is not a COVID-19 vaccine.

53. Arbutus and Genevant's alleged lipid technology has never been included in a COVID-19 vaccine.

PROSECUTION HISTORY OF U.S. PAT. NO. 11,141,378 FAMILY

54. On April 15, 2008, Protiva filed a provisional application, U.S. Provisional Patent Application No. 61/045,228 (the "'228 Application"), with claims that state "[a] nucleic acid-lipid particle comprising: (a) a nucleic acid; [and] (b) a cationic lipid comprising **from about 50 mol % to about 85 mol %** of the total lipid present in the particle." (Emphasis added). In the specification, all examples encapsulating a nucleic acid use only siRNA molecules as the nucleic acid.

55. On April 15, 2009, Protiva filed the first non-provisional patent application in this family, U.S. Patent Application No. 12/424,367 (the "'367 Application"), which originally claimed

after a preliminary amendment "[a] nucleic acid-lipid particle comprising: (a) a nucleic acid; [and] (b) a cationic lipid comprising **from about 50 mol % to about 65 mol %** of the total lipid present in the particle." (Emphasis added). Again, all examples in the specification encapsulating a nucleic acid use only siRNA molecules as the nucleic acid.

56. During prosecution of the '367 Application, the Examiner issued non-final rejections under 35 U.S.C. § 102(b) and 35 U.S.C. § 103(a) for all pending claims as anticipated and obvious in light of another Protiva patent application, U.S. Patent Publication No. 2006/0008910 (the "'910 Publication"). In particular, the Examiner issued a second non-final rejection under §§ 102(b) and 103(a) on May 12, 2011 for all pending claims, finding that "the relative amounts of components read on a broad range of amounts because of the term 'comprising about,'" which "could embrace an amount +/- 10, 20, 30 mol % of a lipid component." The Examiner also found that "the term 'comprising from about' . . . embrace[d] a broad range of SNALP formulations."

57. Following this rejection, Protiva and the Examiner conducted a series of telephonic interviews in which Protiva proposed removing the word "about" to support that the claimed ranges were not anticipated by the '910 Publication. As a result, the Examiner agreed to withdraw the rejections under §§ 102(b) and 103(a). Shortly after the telephonic interviews, Protiva amended the claims on August 11, 2011 to remove the word "about" so that the patent required "a cationic lipid comprising **from 50 mol % to 65 mol %** of the total lipid present in the particle." (Emphasis added).

58. On September 12, 2011, the Examiner issued a Notice of Allowance and the '367 Application issued as U.S. Pat. No. 8,058,069 (the "'069 Patent") on November 15, 2011.

59. From this family, Protiva was issued three additional patents—U.S. Pat. Nos. 8,492,359 (the "'359 Patent"), 8,822,668 (the "'668 Patent"), and 9,364,435 (the "'435 Patent"). Each of those patents continue to exclude the word "about" from the claims reciting molar lipid ratios for the cationic lipid.

60. On December 11, 2020, the FDA issued a publicly available EUA for emergency use of Pfizer and BioNTech's mRNA vaccine (now known as Comirnaty®). The letter of authorization to Pfizer provides the lipids and their amounts per dose for the LNP used in Comirnaty®.

61. On April 12, 2021, four months after the lipids and their amounts per dose for Comirnaty® were made public and nearly thirteen years after Protiva filed the original provisional application, Arbutus (purportedly assigned rights to the patent family) filed a new patent application in this family, U.S. Patent Application No. 17/227,802 (the "'802 Application").

62. The '802 Application purports to claim "[a] nucleic acid-lipid particle consisting essentially of: (a) an RNA; [and] (b) a cationic lipid." The claims of the '802 Application do not expressly recite any numerical values for a molar lipid ratio of the cationic lipid, let alone the "**from 50 mol % to 65 mol %**" or "**from 50 mol % to 85 mol %**" values that were included in the previously issued patents and alleged to be a basis for patentability.

63. Despite not providing an express numerical value limitation as to the molar lipid ratio of the cationic lipid, Claim 1 of the '802 Application does provide an express limitation as to the molar lipid ratio values for all other lipids of the nucleic acid-lipid particle. Upon information and belief, this was a deliberate patent prosecution strategy to make less apparent to the U.S. Patent and Trademark Office that Arbutus and Genevant wished to claim molar lipid ratios of cationic

lipid that were not supported by the patent specification and would, if not included, conflict with their prior positions as to a basis for patentability. For example, Claim 1 as originally filed reads:

> 1. A nucleic acid-lipid particle consisting essentially of: (a) an RNA; (b) a cationic lipid having a protonatable tertiary amine; (c) a mixture of a phospholipid and cholesterol of from 30 mol % to 55 mol % of the total lipid present in the particle; and (d) a polyethyleneglycol (PEG)-lipid conjugate consisting of from 0.1 mol % to 2 mol % of the total lipid present in the particle.

64. In the specification for the '802 Application, all examples encapsulating an RNA use only siRNA molecules as the RNA.

65. On October 12, 2021, the '802 Application issued as the '378 Patent.

66. Arbutus and Genevant sent a letter to Pfizer, copying BioNTech, accusing Pfizer and BioNTech that they may infringe the '378 Patent—despite knowing that the LNP used in Comirnaty® is outside the scope of the claims of the '378 Patent and outside the scope of what Protiva allegedly invented.

67. Arbutus and Genevant have initiated this lawsuit to enforce the '378 Patent against Pfizer and BioNTech seeking damages despite knowing that the LNP used in Comirnaty® is outside the scope of the claims of the '378 Patent and outside the scope of what Protiva allegedly invented.

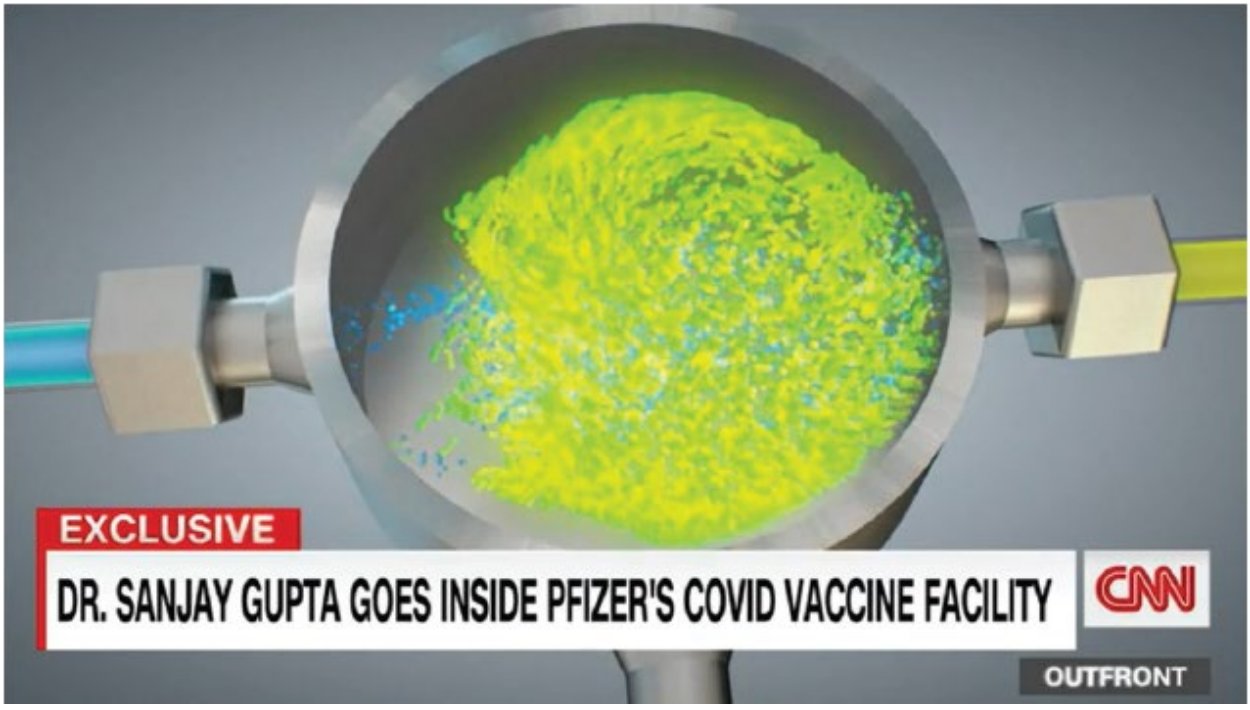
PROSECUTION HISTORY OF U.S. PAT. NOS. 11,298,320 AND 11,318,098 FAMILY

68. On June 28, 2002, Protiva filed a provisional application, U.S. Provisional Patent Application No. 60/392,887 (the "'887 Application"), with claims reciting processes and apparatuses for producing a liposome by mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment. In the specification, all figures and examples in which the organic lipid solution and the aqueous solution are mixed involve introducing them into the mixing environment at the same flow rate.

69. In the following non-provisional patent applications and any patents that issued therefrom directed to processes and apparatuses in this family, all claims directed to flow rates required mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at "substantially equal flow rates" or "about equal flow rates."

70. The Patent and Trademark Office issued three patents to Protiva: U.S. Pat. Nos. 7,901,708 (the "'708 Patent"), 8,329,070 (the "'070 Patent"), and 9,492,386 (the "'386 Patent"). Each patent claims mixing at "about equal flow rates."

71. On March 31, 2021, CNN aired an interview with Pfizer's President of Global Supply as he gave a tour of a Pfizer production facility, during which the below image of a "T-mixer" was shown.



72. In their Complaint, Arbutus and Genevant characterize this image as demonstrating the T-mixer as "a mixing chamber configured to create opposing flows of the aqueous (blue) and

lipid (yellow) solutions at about 180° relative to each other and **at different flow rates relative to each other**." (Emphasis added).

73. On May 25, 2021, less than two months after the CNN interview aired and almost two decades after Protiva filed the provisional application, Arbutus filed new patent applications in this family, U.S. Patent Application No. 17/330,209 (the "'209 Application") and U.S. Patent Application No. 17/329,755 (the "'755 Application").

74. The '209 Application and the '755 Application are the first applications in this family which recite claims for mixing solutions at "different flow rates relative to each other."

75. In the specifications of the '209 Application and the '755 Application, all figures and examples in which the organic lipid solution and the aqueous solution are mixed involve introducing them into the mixing environment at the same flow rate.

76. On April 12, 2022, the '209 Application issued as the '320 Patent.

77. On May 3, 2022, the '755 Application issued as the '098 Patent.

78. Genevant sent email correspondence to BioNTech, copying Pfizer, stating that the '320 and '098 Patents "may be infringed" by BioNTech and Pfizer—despite knowing that the manufacturing process used for Comirnaty® is outside the scope of the claims of those patents and outside the scope of what Protiva allegedly invented.

79. Arbutus and Genevant have initiated this lawsuit to enforce the '320 Patent and '098 Patent against Pfizer and BioNTech seeking damages despite knowing that the manufacturing process used for Comirnaty® is outside the scope of the claims of the '320 Patent and '098 Patent and outside the scope of what Protiva allegedly invented.

COUNT I – DECLARATION OF NON-INFRINGEMENT ('651 PATENT)

80. Counterclaimants incorporate by reference paragraphs 1 through 79 of their Counterclaims as if fully set forth herein.

81. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '651 Patent.

82. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the '651 Patent.

83. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the '651 Patent.

84. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '651 Patent.

85. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT II – DECLARATION OF NON-INFRINGEMENT ('359 PATENT)

86. Counterclaimants incorporate by reference paragraphs 1 through 85 of their Counterclaims as if fully set forth herein.

87. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '359 Patent.

88. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the '359 Patent.

89. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the ’359 Patent.

90. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the ’359 Patent.

91. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys’ fees incurred in connection with this matter.

COUNT III – DECLARATION OF NON-INFRINGEMENT (’378 PATENT)

92. Counterclaimants incorporate by reference paragraphs 1 through 91 of their Counterclaims as if fully set forth herein.

93. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the ’378 Patent.

94. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the ’378 Patent.

95. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the ’378 Patent.

96. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the ’378 Patent.

97. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys’ fees incurred in connection with this matter.

COUNT IV – DECLARATION OF NON-INFRINGEMENT ('320 PATENT)

98. Counterclaimants incorporate by reference paragraphs 1 through 97 of their Counterclaims as if fully set forth herein.

99. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '320 Patent.

100. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the '320 Patent.

101. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the '320 Patent.

102. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the '320 Patent.

103. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys' fees incurred in connection with this matter.

COUNT V – DECLARATION OF NON-INFRINGEMENT ('098 PATENT)

104. Counterclaimants incorporate by reference paragraphs 1 through 103 of their Counterclaims as if fully set forth herein.

105. This Counterclaim arises under the Patent Laws of the United States, 35 U.S.C. § 1 *et seq.* and the Declaratory Judgment Act, 28 U.S.C. §§ 2201 and 2202. An actual, substantial, and continuing justiciable controversy having adverse legal interest of sufficient immediacy and reality to warrant the issuance of a declaration of rights by the Court exists between Counterclaimants and Counterclaim-Defendants concerning the infringement of the '098 Patent.

106. Arbutus and Genevant have accused Counterclaimants of activities that they claim infringe the ’098 Patent.

107. Counterclaimants do not and have not infringed, either directly or indirectly, any claim of the ’098 Patent.

108. Counterclaimants are entitled to a declaratory judgment from this Court that they do not and have not infringed any claim of the ’098 Patent.

109. This is an exceptional case under 35 U.S.C. § 285, entitling Counterclaimants to an award of attorneys’ fees incurred in connection with this matter.

COUNT VI – DECLARATION OF INVALIDITY (’651 PATENT)

110. Counterclaimants incorporate by reference paragraphs 1 through 109 of their Counterclaims as if fully set forth herein.

111. The claims of the ’651 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

112. Counterclaimants are entitled to a declaratory judgment from this Court that the ’651 Patent is invalid.

COUNT VII – DECLARATION OF INVALIDITY (’359 PATENT)

113. Counterclaimants incorporate by reference paragraphs 1 through 112 of their Counterclaims as if fully set forth herein.

114. The claims of the ’359 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of

patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

115. Counterclaimants are entitled to a declaratory judgment from this Court that the '359 Patent is invalid.

COUNT VIII – DECLARATION OF INVALIDITY ('378 PATENT)

116. Counterclaimants incorporate by reference paragraphs 1 through 115 of their Counterclaims as if fully set forth herein.

117. The claims of the '378 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

118. Counterclaimants are entitled to a declaratory judgment from this Court that the '378 Patent is invalid.

COUNT IX – DECLARATION OF INVALIDITY ('320 PATENT)

119. Counterclaimants incorporate by reference paragraphs 1 through 118 of their Counterclaims as if fully set forth herein.

120. The claims of the '320 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

121. Counterclaimants are entitled to a declaratory judgment from this Court that the '320 Patent is invalid.

COUNT X – DECLARATION OF INVALIDITY ('098 PATENT)

122. Counterclaimants incorporate by reference paragraphs 1 through 121 of their Counterclaims as if fully set forth herein.

123. The claims of the '098 Patent are invalid for failure to satisfy one or more of the provisions set forth in 35 U.S.C. §§ 100 *et seq.*, including, without limitation, the requirements of 35 U.S.C. §§ 101, 102, 103, and/or 112 and/or any other judicially created requirements of patentability and enforceability of patent and/or in view of the defenses recognized in 35 U.S.C. § 282.

124. Counterclaimants are entitled to a declaratory judgment from this Court that the '098 Patent is invalid.

COUNT XI – DECLARATION OF PATENT MISUSE ('378 PATENT)

125. Counterclaimants incorporate by reference paragraphs 1 through 124 of their Counterclaims as if fully set forth herein.

126. Arbutus and Genevant have sought to enforce and/or license the '378 Patent for products and acts they know are outside the claims of the '378 Patent.

127. For any claims directed to "[a] nucleic acid-lipid particle comprising . . . a cationic lipid" within a range of molar ratios of the total lipid present in the particle, all family members of the '378 Patent family prior to the filing of the application that resulted in the '378 Patent require a cationic lipid comprising "from 50 mol % to 65 mol %" or "from 50 mol % to 85 mol %" of the total lipid present in the particle.

128. All embodiments encapsulating an RNA in the '378 Patent disclose only siRNA molecules as the RNA, unlike the LNPs used in Comirnaty®.

129. Arbutus only began prosecuting the claims of the '378 Patent, directed to a cationic lipid without any express limitation as to its molar ratio, after the lipid composition of Comirnaty® was published and years after the alleged priority date of the '378 Patent.

130. There is no support for the claims of the '378 Patent in its specification.

131. Arbutus's and Genevant's conduct in seeking to license and enforce the '378 Patent against products and acts they know to be outside the scope of the claims of the '378 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

132. Arbutus and Genevant have engaged in a course of conduct that seeks to broaden the scope of the '378 Patent with anticompetitive effect.

133. Arbutus's and Genevant's misuse of the '378 Patent renders it unenforceable.

COUNT XII – DECLARATION OF PATENT MISUSE ('320 PATENT)

134. Counterclaimants incorporate by reference paragraphs 1 through 133 of their Counterclaims as if fully set forth herein.

135. Arbutus and Genevant have sought to enforce and/or license the '320 Patent for products and acts they know are outside the claims of the '320 Patent.

136. For any claims directed to flow rates, all family members of the '320 Patent family prior to the filing of the application that resulted in the '320 Patent require mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at "substantially equal flow rates" or "about equal flow rates."

137. All Figures in the '320 Patent illustrating flow in the "T-connector" are described as disclosing flow rates that are "substantially equivalent for both lipid and aqueous solution flows."

138. Arbutus only began prosecuting the claims of the ’320 Patent, directed to an apparatus for producing a lipid vesicle by mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at “different flow rates relative to each other,” after CNN aired the interview during which an image of a T-mixer was shown and years after the alleged priority date of the ’320 Patent.

139. There is no support for the claims of the ’320 Patent in its specification.

140. Arbutus’s and Genevant’s conduct in seeking to license and enforce the ’320 Patent against products and acts they know to be outside the scope of the claims of the ’320 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

141. Arbutus and Genevant have engaged in a course of conduct that seeks to broaden the scope of the ’320 Patent with anticompetitive effect.

142. Arbutus’s and Genevant’s misuse of the ’320 Patent renders it unenforceable.

COUNT XIII – DECLARATION OF PATENT MISUSE (’098 PATENT)

143. Counterclaimants incorporate by reference paragraphs 1 through 142 of their Counterclaims as if fully set forth herein.

144. Arbutus and Genevant have sought to enforce and/or license the ’098 Patent for products and acts they know are outside the claims of the ’098 Patent.

145. For any claims directed to flow rates, all family members of the ’098 Patent family prior to the filing of the application that resulted in the ’098 Patent require mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at “substantially equal flow rates” or “about equal flow rates.”

146. All Figures in the '098 Patent illustrating flow in the "T-connector" are described as disclosing flow rates that are "substantially equivalent for both lipid and aqueous solution flows."

147. Arbutus only began prosecuting the claims of the '098 Patent, directed to a process for producing a lipid vesicle by mixing an organic lipid solution with an aqueous solution by introducing them into a mixing environment at "different flow rates relative to each other," after CNN aired the interview during which an image of a T-mixer was shown and years after the alleged priority date of the '098 Patent.

148. There is no support for the claims of the '098 Patent in its specification.

149. Arbutus's and Genevant's conduct in seeking to license and enforce the '098 Patent against products and acts they know to be outside the scope of the claims of the '098 Patent and outside the scope of what was actually invented is an attempt to seek an improper economic benefit.

150. Arbutus and Genevant have engaged in a course of conduct that seeks to broaden the scope of the '098 Patent with anticompetitive effect.

151. Arbutus's and Genevant's misuse of the '098 Patent renders it unenforceable.

JURY DEMAND

Counterclaimants request a trial by jury on all claims so triable in this action.

RELIEF REQUESTED

WHEREFORE, Counterclaimants respectfully request that the Court enter a Judgment and Order in their favor and against Counterclaim-Defendants as follows:

(a) Dismissing Arbutus and Genevant's Complaint with prejudice and denying each and every prayer for relief contained therein;

(b) Declaring that Counterclaimants do not infringe any claim of the Asserted Patents;

(c) Declaring that the manufacture, use, offer to sell, and sale of Comirnaty® within the United States, and its importation into the United States, does not infringe any claim of the Asserted Patents;

(d) Declaring that the claims of the Asserted Patents are invalid;

(e) Declaring that the '378 Patent, '320 Patent, and '098 Patent are unenforceable against Counterclaimants under the doctrine of patent misuse;

(f) Preliminarily and permanently enjoining Arbutus and Genevant and their agents, representatives, attorneys, and those persons in active concert or participation with them who receive actual notice thereof from threatening or initiating infringement litigation against Counterclaimants or any of their customers, dealers, or suppliers, or any prospective or present sellers, dealers, distributors, or customers of Counterclaimants, or charging any of them either orally or in writing with infringement of the Asserted Patents;

(g) Awarding Counterclaimants their attorneys' fees, together with costs and disbursements, including because this case is exceptional under 35 U.S.C. § 285; and

(h) Awarding such other and further relief as the Court deems justified.

Dated: July 10, 2023

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CERTIFICATION PURSUANT TO LOCAL CIVIL RULE 201.1

Pursuant to Local Civil Rule 201.1, the undersigned counsel for Defendants Pfizer Inc. and BioNTech SE certify that this action seeks declaratory and injunctive relief, and therefore this action is not appropriate for compulsory arbitration.

Dated: July 10, 2023

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LOCAL CIVIL RULE 11.2 AND 40.1 CERTIFICATION

Pursuant to Local Civil Rule 11.2, the undersigned counsel for Defendants/Counterclaimants Pfizer Inc. and BioNTech SE state as follows:

Plaintiffs/Counterclaim-Defendants Arbutus Biopharma Corp. and Genevant Sciences GmbH are involved in a proceeding before the U.S. District Court for the Southern District of New York, captioned *Acuitas Therapeutics Inc. v. Genevant Sciences GmbH et al.*, No. 22-2229 (S.D.N.Y.), relating in part to the infringement and validity of U.S. Patent Nos. 9,504,651; 8,492,359; and 11,141,378. The validity and infringement of those same patents is also at issue in this action.

Plaintiffs/Counterclaim-Defendants Arbutus Biopharma Corp. and Genevant Sciences GmbH are also involved in a proceeding before the U.S. District Court for the District of Delaware, captioned *Arbutus Biopharma Corp. et al. v. Moderna, Inc. et al.*, No. 22-252 (D. Del.), relating in part to the infringement and validity of U.S. Patent Nos. 9,504,651; 8,492,359; and 11,141,378. The validity and infringement of those same patents is also at issue in this action.

Except for the foregoing, the matter in controversy in this action is not the subject of any other action in any other court, or of any pending arbitration or administrative proceeding.

Dated: July 10, 2023

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